UNITED STATES DISTRICT COURT
FOR DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA, and the STATES of CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, LOUISIANA, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VIRGINIA, WISCONSIN, the DISTRICT OF COLUMBIA, *ex rel.* ADAM WITKIN, Plaintiffs, vs. MEDTRONIC, INC. and MEDTRONIC MINIMED, INC., Defendants.	No. 1:11-cv-01790-DPW Judge Douglas P. Woodlock

SECOND AMENDED COMPLAINT

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This is an action to recover damages and civil penalties on behalf of the United States of America and certain Commonwealths and States arising from acts by Defendants Medtronic, Inc. and Medtronic MiniMed, Inc. (collectively "Medtronic" or "Defendants") to submit and cause the submission of false claims to federal and state healthcare programs ("government healthcare programs") in violation of the United States Civil False Claims Act, 31 U.S.C. §§ 3729–33, and the False Claims Acts of the above-named States (together referred to as "FCA"). Mr. Witkin also brings claims on behalf of himself under the False Claims Act and state law for damages resulting from Medtronic's unlawful retaliation after he engaged in internal reporting of Medicare fraud.

SUMMARY OF ALLEGATIONS

1. This action involves false claims submitted to government healthcare programs for insulin and insulin pumps for diabetic government healthcare beneficiaries, which account for more than half of all Americans with diabetes.

2. Government healthcare programs reimburse claims for payment pursuant to certain pre-conditions that are set forth in healthcare statutes and regulations. Every provider and supplier in the government healthcare system, including Medtronic, agrees to comply with these conditions in order to be paid for the provision of items or services to government healthcare beneficiaries.

3. The submission of claims to government healthcare programs while in knowing violation of material conditions of payment renders the resulting claims false and violates the False Claims Act (FCA). "Material" under the FCA means that it is capable of influencing the Government's decision to pay the claim.

4. Relator alleges that Medtronic improperly incentivized providers, practices

and diabetes centers in violation of material conditions of payment in order to induce them to order diabetic pumps and supplies. Relator alleges that Medtronic embarked on this strategy of inducements in order to reach the Type 2 diabetic market, a growing market that has been traditionally out of reach of insulin pump manufacturers. (While Type 1 diabetics do not naturally produce insulin and are generally diagnosed in childhood, Type 2 diabetics are those whose bodies have become resistant to insulin over time. Type 2 diabetics are often overweight, disabled, or have other chronic conditions and comorbidities).

5. Insulin pump therapy is a relatively recent addition to the treatment of diabetes. Pump therapy was first approved for Medicare coverage in 1999. Pump therapy is widely viewed as appropriate only for patients with Type 1 diabetes. Type 1 diabetics comprise between five percent and 10% of the universe of Americans with diabetes. The remaining 90-95% suffer from Type 2 diabetes, and the Type 2 population is growing at a frenzied pace. Thirteen million Medicare beneficiaries had been diagnosed as Type 2 diabetics in the United States in 2010, nearly double the number in 2004. These represent more than half the American diabetic population.

6. The standard of care for the treatment of the vast majority of Type 2 diabetics is the self-administration of multiple daily injections of insulin ("MDI" therapy). Centers for Medicare and Medicaid Services Decision Memo for Insulin Pump: C-Peptide Levels as a Criterion for Use (CAG-0092R) (December 17, 2004) ("CMS Decision Memo"). Insulin infusion pumps are considered experimental and investigational for all persons with Type 2 diabetes. *Id.*, *citing* Aetna Clinical Policy Bulletin #0161.

7. In recognition of this, Medicare concluded that the "use of the [insulin pump] is rarely indicated in [Type 2 patients] and . . . strict criteria should be used for eligibility." *Id.* Thus, Medicare only covers insulin pump therapy for Type 2 diabetics if their condition is so severe that their laboratory tests satisfy Medicare pre-conditions for insulin dependence (in essence, mimicking a Type 1 diabetic).

8. In order to continue to increase sales, Medtronic recognized that because the number of Type I diabetics is fairly static, it could increase sales only by "expand[ing] indications" for the use of its pumps (*e.g.,* October 2009 sales email re Best Practices). As a result, Medtronic developed a national sales strategy to increase the new patients to pump therapy ("NPT")—primarily Type 2 and newly-diagnosed pediatric patients—by creating a plethora of incentives and misinformation for providers treating diabetes patients.

9. To reach this growing market, Medtronic incentivized the gatekeepers, those in a position to prescribe pump therapy, through remuneration schemes and through misleading information about the appropriateness of the resulting claims – all in violation of material conditions of payment applied by government healthcare programs.

I. Remuneration Schemes in Violation of AKS and Stark.

10. First, Medtronic offered and paid remuneration to referral sources in violation of the Anti-Kickback Statute ("AKS") and the Stark Statute ("Stark"), with a purpose of inducing referrals of its insulin pump. Compliance with the AKS and Stark laws is a material condition of payment of government healthcare programs. *United States ex rel. Hutcheson v. Blackstone Med. Inc.*, 647 F.3d 377 (1st Cir. June 1, 2011).

11. By offering remuneration to referral sources, Medtronic formed a financial relationship under the Stark laws, the mere existence of which bars the submission of any claims for government healthcare services referred by the provider with which Medtronic has a financial relationship. The statute specifically provides that such claims may not be submitted by the entity or paid by the United States.

12. By offering remuneration to referral sources, Medtronic's relationships are subject to the scrutiny of the AKS, which prohibits the offer or payment of remuneration if even one purpose of the arrangement is to induce the referral of government healthcare programs items and services. And, "neither a legitimate business purpose for the arrangement, nor a fair market value payment, will legitimize a payment if there is also an illegal purpose (*i.e.*, inducing Federal health care program business)." Office of Inspector General (OIG) Supplemental Compliance Guidance for Hospitals, 70 Fed. Reg. 4858, 4864 (January 31, 2005).

13. Medtronic offered several types of remuneration to its referral sources. It offered to set up and manage clinics, called iPro clinics, at the offices of a referral source in order to schedule sessions with their diabetic patients on insulin injections. During these sessions, Medtronic would insert a subcutaneous sensor under their skin (such as in the abdomen or groin) as part of its professional continuous glucose monitoring (CGM) system (called iPro) in order to monitor the patient's glucose level for a period of days. Medtronic directed its representatives to perform these procedures instead of the physician (though they are not licensed to do so), and put itself in the position of the trusted medical professional in the patient's eyes.

14. Medtronic's purpose in setting up these clinics was to be able to incentivize the doctor (and the patient) to convert to pump therapy using the Medtronic pump. In order to do that, Medtronic sold these sessions as a revenue opportunity, because the provider could bill professional services associated with setting up and interpreting the CGM, as well as with converting a patient to pump therapy.

15. Under the iPro system, Medtronic personnel are directed to become "Business Consultants" to the office, and provide an "Economic Model" which shows the revenue opportunity for the practice by using a physician's own patient numbers and government payor mix to model how much annual revenue was available to the provider by (1) permitting Medtronic to run the "clinics;" and (2) by converting patients to the pump. In addition to the revenue opportunity which these practices afforded the physician, Medtronic assists in or takes over the provision of services so that the billing and the ordering of the pump is accomplished with minimal effort by the provider.

16. Medtronic offered an array of incentives to make the ordering of its products more lucrative for its targeted providers. Because Medicare offered low reimbursement for the training and education of new pump candidates, Medtronic offered and paid training fees to individual providers, practices and centers at higher rates and for amounts of time that were neither needed nor actually rendered. As described further herein, such payments were many multiples of the amounts that a provider may obtain from Medicare for the same work.

17. Medtronic also offered and provided other free incentives, such as the services of a Medtronic nurse in a physician's office, or free lunches, dinners, or luxury trips.

18. Each of these incentives was provided with a purpose of inducing referral sources to order Medtronic pumps. As Medtronic documents reflect, such incentives (like the iPro clinics) are "the foundation of our business" to get new pump orders. These economic tools were used to get providers "to sign on the line that is dotted" (the Medtronic order form) and to obtain "Medtronic loyalty."

19. The intended result of these schemes was the submission and payment of government healthcare claims. Medtronic knew that each of its targeted providers treated government healthcare beneficiaries, and indeed, carefully tracked that information. Medtronic knew that its offer of remuneration to these providers precluded the submission of claims under Stark, and subjected it to scrutiny under the AKS. Medtronic knew that it violated AKS laws by offering these incentives when even one purpose was to induce the referral of more patients for pump therapy.

20. The resulting claims from incentivized referral sources are false. They were submitted while Medtronic was in knowing violation of Stark and AKS laws, a material condition of payment of government healthcare claims. Medtronic's actions are capable of influencing the government's decision to pay the claims and, as such, are false claims under the FCA.

21. Representative examples of those claims are identified *infra* in § I.C.2.

II. <u>Claims for Off-Label Uses Which are Not Safe and Effective</u>.

22. Medtronic also provided physicians with false and misleading information regarding the safety and effectiveness of the off-label use of a high concentration insulin, U-500, with the pump and the off-label use of its adult pump in pediatric patients.

23. Government healthcare program do not pay for drugs or medical devices unless they are reasonable and necessary for treatment of patients. "Reasonable and necessary" claims are those which are both safe and effective for use and appropriate for the patient's medical need. Medicare Program Integrity Manual, § 13.5.1 (January 15, 2013).

24. Unlabeled uses of a drug are presumptively not safe and effective under Medicare, and can be covered by Medicare only in the circumstance in which "the carrier determines the use to be medically accepted, taking into consideration the major drug compendia, authoritative medical literature and/or accepted standards of medical practice." *Id.* at 50.4.2. Medicaid even more stringently restricts coverage of drugs to those which are FDA-approved and used for approved medical indications, unless such indications have been recognized by the major drug compendia.

25. The off-label use of U-500 insulin in insulin pumps is not supported by any major drug compendia, by any authoritative medical literature, or by any demonstration of the safety and efficacy of this off-label use. Yet Medtronic promotes the use of its pumps with U-500 insulin as safe and effective, using misleading information and sham internal studies of patient success to induce providers to use the pump off-label in order to accommodate Type 2 patients who need large doses of insulin (and for whom the pump with its limited reservoir would be ineffectual and inappropriate).

26. In fact, safety issues have been associated with the use of U-500 insulin. Such safety issues are significantly exacerbated by the fact that daily injections, rather than pump use, are the standard of care for Type 2 patients because use of the pump

creates an inherent risk of an over-delivery of insulin that is made worse when more concentrated forms of insulin are administered than has been approved by FDA.

27. Medtronic also uses misleading information to induce the off-label use of the adult pump for pediatric patients. Though the FDA has specifically identified that the adult pump may not be safe and effective for pediatric patients because its glucose sensors are not set appropriately for a child (and may alert the patient of a hypoglycemic event too late), Medtronic exclusively promotes its adult pump, without regard to whether the beneficiary is a pediatric patient.

28. Medtronic misleads providers and parents by promoting that its pump is indicated for pediatric use (while other competitors with adult pumps are "contraindicated"), and by representing that the glucose sensor alerts will let parents sleep at night, yet providing and shipping only the adult pump when the pump has been prescribed for a child. Because Medtronic has control of the claims process, it is able to inappropriately influence the resulting order.

29. Medtronic engages in this bait-and-switch because it determined, internally, that it was unable to sustain pediatric pump sales because the FDA's sensor requirements led to frequent sensor alerts in the night and rebuffed parents from continued use of the pump.

30. Submission and payment of false claims to government healthcare programs are the foreseeable and intended result of these practices.

31. Medtronic's practice of misleading providers regarding the safety and efficacy of off-label use of its insulin pump violated material conditions of payment of the resulting claims. Medtronic's actions are capable of influencing the government's

decision to pay the claims, in fact did influence such decisions, and thus resulted in submission and payment of false claims under the FCA.

32. Representative examples of those claims are identified *infra* § II.B.2, D.2..

III. Ineligible Claims for Type 2 Patients.

33. To induce more referrals and resulting claims for insulin pumps for Type 2 patients, Medtronic made material misrepresentations to physicians and government healthcare programs regarding the eligibility of Type 2 patients for the insulin pump, and the appropriateness of the pump for their treatment.

34. Claims for insulin pumps for Type 2 patients are eligible for reimbursement only if they meet Medicare's strict coverage criteria: namely, that the beneficiary's laboratory results reflect that his or her insulin resistance is very close to that of a Type 1 patient, and that the beneficiary has a demonstrated history of compliant glucose self-testing. Medicare Coverage Issues Manual, § 60-14 (September 2001); National Coverage Determination § 280.14 (February 18, 2005).

35. Notwithstanding these specific criteria, Medtronic advised its sales force that its goal is that "HCP [healthcare provider] promotes IPT [insulin pump therapy] as the standard of care for *all insulin-requiring patients*." As stated in Medtronic's corporate training material: "For an account to maximize its potential, it must understand and believe in all of the indications of pump therapy, promote the therapy to *all insulin requiring patients*, and *not limit the therapy to specific patient types*." Therapy Driver Account Profile (emphasis supplied).

36. To serve this end, Medtronic directed its sales force to use misleading information to induce providers to order the pump for their Type 2 patients. Once

Medtronic persuaded the physician of the false proposition that the pump was appropriate for all insulin-dependent patients, Medtronic prepared the documentation supporting the eligibility of the claim under government healthcare programs. This included interviewing patients regarding their glucose-testing habits and then documenting the purported medical eligibility of each claim.

37. Having gained control of this interview process, Medtronic falsified information to support the eligibility of the patient for coverage. This conduct includes preparing documentation of a false history of testing by the patient, coupled with coaching patients how to acutely alter their glucose levels to produce eligible laboratory results, by carb-fasting or over-delivering insulin prior to taking the test.

38. The false claims to government healthcare programs that resulted were the foreseeable and intended result of these schemes.

39. Medtronic's practice of providing misleading information to providers to both induce the pump order and falsify the eligibility of the resulting claim violates the material conditions under which government healthcare programs provide reimbursement for the use of an insulin pump. Medtronic's actions were capable of influencing the government's decision to pay the claims; did in fact influence those decisions, and resulted in submission and payment of false claims.

40. Representative examples of such claims are identified *infra* in § III.D.2.

IV. Causal Link and Representative Claims.

41. As demonstrated herein, each of these schemes violated material conditions of payment of government healthcare claims. Claims submitted while in violation of material conditions of payment are false claims.

42. Medtronic's schemes were intended to influence the submission of claims for its insulin pump, in violation of material conditions of payment of Medicare, Medicaid and other federal healthcare insurance programs. Medtronic's actions were capable of influencing the government's decision to pay the resulting claims, and in fact did improperly influence such decisions. Such actions thus violate the False Claims Act.

43. In deference to the Court's request for a demonstration of the causal link between the schemes alleged and the resulting claims, such description has been provided for each area of allegation:

Violations of AKS and Stark, Section I

- Causal Link and Representative Examples, Section I.C

Violations of the Conditions of Payment for Off-Label Uses, Section II

- Causal Link and Representative Examples, Section II.B.,D

Violations of the Conditions of Payment for Type 2 Patients, Section III

- Causal Link and Representative Examples, Section III.D

44. Hyperlinks have been provided throughout this document to assist with navigation between sections.

PARTIES

45. *Qui tam* plaintiff-relator Adam Witkin ("Relator") is a resident of the State of Oregon. He was employed by Medtronic from November of 2004 until his retaliatory termination on February 28, 2011. Relator worked within the Diabetes Division of Medtronic, and held the position of Territory Manager and then Senior Territory Manager for the Eugene Territory, which covers most of Oregon other than Portland. In that capacity, Mr. Witkin was responsible for the sale of Medtronic's medical devices for

the treatment and management of diabetes. The facts alleged herein are based on Mr. Witkin's personal knowledge and on documents and information in his possession.

46. The Government plaintiffs in this lawsuit are the United States and the States of California, Colorado Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Maryland, Michigan, Minnesota Montana, Nevada, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Wisconsin, the Commonwealths of Massachusetts and Virginia, and the District of Columbia (collectively "the States").

47. Defendant Medtronic, Inc. is a Delaware corporation with its corporate headquarters and principal place of business in Minneapolis, Minnesota. It is a publicly held Fortune 200 company that develops, manufactures and markets medical devices. Medtronic promotes and sells its devices in this District, across the United States, and around the world. Medtronic had approximately $16.1 billion in revenue for fiscal year 2012, including approximately $1.48 billion in revenue from its Diabetes Operating Segment.

48. Defendant Medtronic MiniMed, Inc. ("MiniMed") is a Delaware corporation with its principal place of business in Northridge, California. MiniMed is a wholly-owned subsidiary of Medtronic, Inc. MiniMed manufactures, markets, and sells medical devices for the treatment and management of diabetes, including the devices that are the subject of this Complaint.

49. References in this complaint to "Medtronic" refer collectively to Medtronic, Inc. and Medtronic MiniMed, Inc.

JURISDICTION AND VENUE

50. Jurisdiction is based on 28 U.S.C. § 1331, 28 U.S.C. §1367, and 31 U.S.C. § 3732, the latter of which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. § 3730. In addition, 31 U.S.C. § 3732(b) specifically confers jurisdiction on this Court over the state law claims asserted in this Complaint.

51. This Court has personal jurisdiction over defendants, pursuant to 31 U.S.C. § 3732(a), because that section authorizes nationwide service of process and because defendants have minimum contacts with the United States. Moreover, one or more of the defendants can be found in, reside in, and/or transact business in this judicial district.

52. Venue is proper, pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. § 1391(b)–(c), because one or more of the defendants can be found in, reside in, and/or transact business in this judicial district. In addition, statutory violations, as alleged herein, occurred in this judicial district.

53. The allegations of this Complaint have not been publicly disclosed in a criminal, civil, or administrative hearing, nor in any congressional, administrative, or General Accounting Office report, hearing, audit, or investigation, nor in the news media. Moreover, even if such a public disclosure had occurred, this Court would retain jurisdiction over this matter because Relator is the original source of the information upon which this Complaint is based, as that phrase in used in the False Claims Act and other laws at issue herein.

54. Relator provided disclosure of the allegations of this Complaint to the

United States and the States prior to filing under the federal False Claims Act and state False Claims Acts, respectively.

BACKGROUND

I. The False Claims Act.

55. The federal FCA imposes liability on any person who (A) "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;" or (B) "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(A)-(B). Violations are subject to a civil penalty of up to $11,000 for each such claim, plus three times the amount of the damages sustained by the Government. The state FCAs contain comparable provisions imposing liability and providing for recovery of penalties and damages.

56. The federal and state FCA's also contain anti-retaliation provisions, prohibiting discrimination against a person in the terms and conditions of employment because of that person's efforts in furtherance of an action under that statute or efforts to stop one or more violations of the False Claims Act. Relator's retaliation claims under federal and state laws are discussed in Section V, *infra*.

57. The FCA reaches "all fraudulent attempts to cause the Government to pay [out] sums of money or to deliver property or services." S. Rep. No. 99-345 at 9 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5266, 5274. The Supreme Court has consistently reaffirmed that the FCA is a remedial statute that should be construed broadly. *United States v. Neifert-White*, 390 U.S. 228, 232 (1968).

58. Courts have consistently held that knowingly submitting or causing the submission of claims resulting from a violation of a material condition of payment creates FCA liability. *U.S. ex rel. Hutcheson v. Blackstone Med. Inc.*, 647 F.3d 377, 379-80 (1st Cir. June 1, 2011). FCA liability arises when (1) a defendant acts knowingly and (2) the claim's defect is material, meaning that it has "a natural tendency" to influence the government to pay a claim. *Hutcheson*, 647 F.3d at 388.

59. A "claim" under the FCA includes any request or demand for money under government healthcare programs. 31 U.S.C. §§ 3729(b)(2).

60. The material conditions under which Government healthcare programs will pay claims for items and services provided to its beneficiaries are spelled out in government healthcare statutes and regulations.

II. Items and Services at Issue.

A. Treatment of Diabetes: Type 1 Versus Type 2.

61. Diabetes is a condition in which the body is not able to regulate levels of glucose (sugar) in the blood, resulting in too much glucose being present in the blood. An estimated 26 million Americans have diabetes.

62. In Type 1 diabetes, traditionally diagnosed in children or young adults, the body does not produce enough insulin, which is a hormone produced by the pancreas that aids in moving glucose from the blood to the cells.

63. Type 1 diabetes is an autoimmune disease. While it is one of the more common chronic illnesses in children, Type 1 diabetes afflicts less than 10% of all diabetes patients; the remaining suffer from Type 2 diabetes, which is an entirely-different illness from type 1.

64. In Type 2 diabetes, insulin that the body produces is inefficient at moving glucose from the blood to the cells. Some glucose is moved out of the bloodstream, but not as effectively as a person with normal insulin efficiency. This results in high blood sugar. Type 2 diabetes is most common in people who are overweight and obese, and in older populations. According to the American Diabetes Association, about 90 to 95% of all diabetes cases are Type 2.

65. Type 2 diabetes was until recently considered an adult disease. However, with obesity rates more than tripling among adolescents since 1990, the incidence of Type 2 diabetes has rapidly increased among young people.

66. All people, with or without diabetes, need insulin for two reasons: (1) a background amount of insulin for normal functions of the body without food, and (2) a burst of insulin "on demand" when food is eaten. People without diabetes can trust that their pancreas will produce the required amount of insulin for them. People with diabetes need to take insulin as similar as possible to the way their pancreas would produce it if it could.

67. A person with a serious case of diabetes, *i.e.*, significant insulin deficiency, typically needs to take multiple daily injections of insulin. A common regimen involves four daily injections – before breakfast, lunch, and supper, and before bedtime. With multiple daily injections, some of the insulin is being used for background and some is being used for food digestion.

68. An alternative to multiple daily injections ("MDI") is insulin infusion pump therapy. An insulin infusion pump is a small device that delivers insulin continuously to the body. The insulin is delivered according to a program that is adjusted to each

insulin pump wearer. A small amount of insulin is given continually (the "basal rate"). This insulin keeps blood glucose in the desired range between meals and overnight. When food is eaten, the user programs the insulin pump to deliver a "bolus dose" of insulin matched to the amount of food that will be consumed.

69. Historically, insulin pump sales have been targeted almost exclusively to Type 1 diabetes patients, which is only a very small segment of the diabetes market. Consistent with Medicare's stringent coverage requirements for the pump, most physicians do not consider insulin-dependent Type 2 diabetics as pump candidates because the standard of care for these patients is MDI therapy.

70. An insulin pump wearer decides how much insulin will be delivered based upon the results of blood glucose monitoring. The standard home method of blood glucose monitoring is a fingerstick test. This is a do-it-yourself test using a blood glucose meter that measures blood sugar at the time of the test. The individual "sticks" a finger to obtain blood for the test.

71. A more recent development is the use of "continuous glucose monitoring" (CGM) devices. These devices use a "sensor" inserted under the skin, which continually monitors and measures glucose levels in the bloodstream. The sensor connects directly to a small transmitter, which wirelessly sends the glucose data to a small monitoring device, recorder, or insulin pump. The CGM device is used to detect trends and track patterns in glucose levels for the purpose of making both acute and long-term therapy adjustments. In order to produce a interstitial glucose value, the CGM device must be calibrated with blood glucose values from a blood glucose meter.

72. The primary medical specialists who treat diabetes patients are

endocrinologists and internists.

B. Diabetes Drugs and Devices.

73. Medtronic sells products for the treatment and management of diabetes. In fiscal year 2012, Medtronic's total worldwide sales for its diabetes products were $1.48 billion, an increase of almost 20% since the filing of this Complaint (in 2011).

74. Medtronic sells insulin pumps, personal and professional glucose monitoring devices, and other diabetic supplies. Government healthcare programs reimburse for the use of insulin pumps, and attendant supplies (such as infusion sets, reservoirs, surgical tape and test strips), and the insulin used in the pumps, subject to certain preconditions, but generally do not reimburse for continuous glucose monitoring devices.

75. In addition to its line of devices, Medtronic's sales practices result in sales of other items and services which are also paid for by government healthcare programs, including physician services resulting from the evaluation and management of patients using is its devices**.**

76. For the purposes of the allegations herein, the government healthcare claims at issue are claims resulting from orders of Medtronic's insulin pump (and required supplies), prescriptions for the insulin used in the pump, and the treating physician's associated professional services.

1. Medtronic's Insulin Pumps.

77. The current models of Medtronic's insulin infusion pump are called the Paradigm Revel ("Revel") 523 and 723. The only difference between the Revel 523 and 723 is the size of the insulin reservoir – the Revel 523 holds 176 units of insulin and the

Revel 723 holds 300 units of insulin. The pediatric models are Revel 523k and Revel 723k. Older versions of the pump had the model numbers 522 and 722 (and 522k and 722k for pediatric patients).

78. Medtronic's "MiniMed Paradigm REAL-Time System" (hereafter, "Paradigm RT") combines Medtronic's insulin pump with Medtronic's glucose sensor into an integrated system. The sensor communicates with the pump, and data from the sensor can be downloaded through software called "Carelink," which allows the data to be viewed in a computer for patient or physician use. The pump provides an alert if the sensor detects that glucose levels fall below or rise above preset values. The pump monitor provides a trend graph to show current glucose trends.

79. As used herein, Medtronic's "insulin pump" refers to all models of insulin infusion pumps sold by Medtronic over time. When a physician places an order for a pump, Medtronic ships the latest available model.

80. Medtronic's insulin pump is indicated for the continuous delivery of insulin, at set and variable rates, for the management of diabetes in persons requiring insulin.

81. Medtronic's insulin pump is about the size of a compact cell phone. It is worn outside the body in a pocket, underneath clothing in a pouch, or on a belt like a phone. The insulin is contained in a receptacle called the "insulin reservoir."

82. The insulin pump delivers insulin from the reservoir into the user's body through a tiny, soft tube (thinner than a strand of spaghetti), which is called the "infusion set." At the end of the tube is an even smaller, softer tube called a cannula, which is approximately a half inch in length. The cannula is inserted under the skin by a needle.

83. The current retail price of Medtronic's insulin pump is approximately $6,500 to $9000. The pump reservoir and infusion sets are disposable devices. They are supposed to be replaced every two to three days. The current retail price of a monthly supply of reservoirs and infusion sets is approximately $200 per month.

2. Insulin Promoted by Medtronic.

84. Medtronic's pump is approved for use with Humulin R U-100 ("U-100") insulin, which means there are 100 units of insulin per milliliter of fluid in the vial. Medtronic represented to the FDA that the pumps "are designed to deliver 0.00 to 35.00 units of U100 insulin per hour in basal rates and up to 25.00 units of U100 insulin per meal or meal bolus." Similarly, other manufacturers' insulin pumps are also only approved by the FDA for use with U-100 insulin.

85. The insulin is not manufactured by Medtronic, and is separately prescribed by the physician.

86. Medtronic exclusively promotes insulin manufactured by Eli Lilly, a pharmaceutical manufacturer with which Medtronic formed a strategic alliance for the purposes of insulin promotion.

87. As alleged further below, Medtronic improperly promotes a higher concentration insulin manufactured by Eli Lilly, U-500, to be used with its pump, notwithstanding that neither the U-500 insulin nor its pump is approved for that use. Rather, U-500 insulin, a form of insulin with five times the concentration of U-100, is approved only for use as an injection. Medtronic also exclusively promotes U-500 insulin – it is not independently promoted by Eli Lilly.

88. Lilly provides Medtronic with marketing money for programs to

incentivize physicians to order Medtronic's pump with its insulin.

III. Government HealthCare Programs.

89. An estimated 26 million Americans have diabetes, and at least half of those are government healthcare program beneficiaries. This is an alarmingly growing market: In 2004, for example, the Center for Medicare and Medicaid Services ("CMS") estimated that more than 20%, or 6.3 million, of the 31.3 million Medicare beneficiaries in the United States had diabetes.[1] By 2010, Medicare beneficiaries with diabetes more than doubled that number, rising to 13 million.[2] At that rate, by 2020, it is estimated those numbers will rise to 21 million.[3]

90. The Medicare program is administered by CMS on behalf of the Secretary of HHS (the "Secretary"). Medicare "Part A," 42 U.S.C. §§ 1395*c*-1395*i*, provides insurance for covered inpatient hospital and related services. Medicare "Part B," 42 U.S.C. §§ 1395*j*-1395*w*, is a supplemental program insuring other items and services, such as out-patient hospital and physician services, supplies, and laboratory tests. Medicare Part C covers certain managed care plans, and Medicare Part D provides subsidized prescription drug coverage for Medicare beneficiaries.

91. Medicare Part B is the part of the program that covers most of the items and services described herein. When provided in accordance with Medicare conditions of payment, Medicare Part B covers external insulin pumps for a limited set of eligible

[1] Adler, Gerald S. Centers for Medicare and Medicaid Services, Diabetes in the Medicare Aged Population, 2004, *available at* http://www.cms.gov/Research-Statistics-Data-and-Systems/Research/HealthCareFinancingReview/downloads/07-08Winterpg91.pdf

[2] Working Paper 5 at p.10-11, The United States of Diabetes: Challenges and Opportunities In the Decade Ahead (November 2010), *available at* http://www.unitedhealthgroup.com/hrm/UNH_WorkingPaper5.pdf.

[3] *Id.*

beneficiaries (generally Type 1 patients and a subset of Type 2 patients whose insulin-resistance mimics Type 1), the prescription for insulin when used in conjunction with the pump, home blood glucose monitors, disposable supplies (such as infusion sets and reservoirs), professional services associated with professional continuous glucose monitoring ("GCM"), diabetic self-management training (DSMT) services, and the professional services which may be rendered by physicians in the treatment of diabetes (including evaluation and management ("E&M") services provided in conjunction with the use of an insulin pump).[4]

92. Medicare Part B generally pays for the drugs and devices at issue at 80% of the allowable charge. For physician services, Medicare uses reimbursement rates calculated and published annually by CMS, based on location of the provider, using Current Procedural Terminology ("CPT") codes.

93. Medicaid is a public assistance program providing for payment of medical expenses for the poor and disabled. Funding for Medicaid is shared between the federal government and state governments. For dual-eligible patients (those eligible for both Medicaid and Medicare), Medicaid pays the deductible for Medicare patients.

94. Although Medicaid is administered on a state-by-state basis, the state programs generally adhere to federal guidelines. The federal Medicaid statute sets forth the minimum requirements for state Medicaid programs to qualify for federal funding, which is called federal financial participation. 42 U.S.C. §§ 1396, et seq. Under these

4 *E.g.,* Local Coverage Summary, United Healthcare Medicare Advantage Plans, Diabetes Management, Equipment and Supplies. available at https://www.unitedhealthcareonline.com/ccmcontent/ProviderII/UHC/en-US/Assets/ProviderStaticFiles/ProviderStaticFilesPdf/Tools%20and%20Resources/Policies%20and%20Protocols/UnitedHealthcare%20Medicare%20Coverage/Diabetes_Management_SH_Ovations.pdf

minimum requirements, Medicaid also provides coverage for the use of medical devices, including (subject to conditions) Medtronic's external infusion pump and insulin. 42 C.F.R. § 440.70.

95. In addition to Medicare and Medicaid, the federal government provides reimbursement, in whole or part, for approved drugs and medical devices under several other federal health care programs, including, but not limited to, CHAMPUS/TRICARE, CHAMPVA, the Federal Employees Health Benefit Program, and the Indian Health Service.

96. CHAMPUS/TRICARE, administered by the United States Department of Defense, is a health care program for individuals and dependents affiliated with the armed forces. CHAMPVA, administered by the United States Department of Veterans Affairs, is a health care program for the families of veterans with 100 percent service-connected disabilities. The Federal Employee Health Benefit Program, administered by the United States Office of Personnel Management, provides health insurance for federal employees, retirees, and survivors. The Indian Health Service, administered by the Department of Health and Human Services, provides health services to Native Americans.

97. Government healthcare programs establish the material terms and conditions under which providers and suppliers may submit claims to government healthcare programs.

98. The material conditions of payment pertinent to Relator's allegations (and described more specifically herein) are:

- Compliance with the AKS and Stark Laws (Section I.A.);
- Compliance with the statutory and regulatory requirement that all uses of medical devices be reasonable and necessary (and, in turn, safe and effective) for treatment of patients; and that all drugs be used for FDA-approved on-label uses or only off-label uses recognized by the major drug compendia or documented by nationally-accepted sources as safe and effective (Section II.A.); and
- Compliance with the coverage criteria governing the eligibility of only Type 1 and a limited subset of Type 2 beneficiaries for use of an insulin pump (Section III.A.);

99. Every provider and supplier agrees to comply with those terms and conditions in order to be eligible to provide services or supplies to government healthcare program beneficiaries.

100. The failure of compliance with those conditions would have a natural tendency to influence the Government's decision to pay those claims, and results in false clams.

FACTUAL ALLEGATIONS

I. FALSE CLAIMS RESULTING FROM AKS AND STARK VIOLATIONS.

A. Compliance with the Anti-Kickback Statute and Stark Laws is a Condition of Payment of Government Healthcare Programs.

101. In order to submit claims to government healthcare programs, providers and suppliers must be in compliance with the Anti-Kickback Statute ("AKS") and the Stark Statute ("Stark").

102. The AKS, codified at 42 U.S.C. § 1320a-7b(b), prohibits any person or entity from offering or providing "any remuneration" to induce or reward any person for referring, recommending or arranging for the purchase of any item for which payment may be made under a federally-funded health care program. 42 U.S.C. § 1320a-7b(b).

103. A claim "that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim" for purposes of the False Claims Act. 42 U.S.C § 1320a-7b(g).

104. Stark, codified at 42 U.S.C. § 1395nn, prohibits a physician from making referrals for certain "designated health services" (including medical devices) payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship, unless an exception applies.

105. Financial relationships which are prohibited under Stark include arrangements involving remuneration between a physician (or an immediate family member of such physician) and such an entity. 42 U.S.C. §§ 1395nn(a)(2)(B), (h)(1)(A).

106. Stark is a strict liability statute. It prohibits payment of any claim submitted to the United States for a designated health service provided in violation of its provisions. § 1395nn(g)(1). If a prohibited financial relationship exists, "the entity may not present or cause to be presented a claim" for designated health services. 42 U.S.C. §§ 1395nn(a)(1)(B).

107. In addition to these clear statutory proscriptions, every provider and supplier who supplies items and services to government healthcare beneficiaries certify their understanding that payment of claims are conditioned upon the "underlying transaction complying with … the Federal Anti-Kickback Statute and the Stark law…." Provider/Supplier Agreement, Form CMS-855.

108. Thus, claims submitted in violation of the AKS and Stark violate material conditions of payment of government healthcare programs, and are false claims under the FCA.

109. In order to establish a violation of the Stark Statute, relator must allege that Medtronic had a relationship with the physician involving any remuneration between it and the physician.

110. In order to establish a violation of the AKS, relator must allege that Medtronic knowingly and willfully: (1) offered or paid remuneration of any kind, directly or indirectly; which was (2) intended in any part to induce the utilization of federal healthcare services.

111. The term “remuneration” includes anything of value, in whatever form, whether in cash or in kind, or offered directly or indirectly.

112. “Intent to induce” is shown if one purpose of payment was to induce referrals of federal healthcare business. *United States v. Bay State Ambulance & Hosp. Rental Serv.*, 874 F.2d 20, 30 (1st Cir. 1989).

113. “Intent to induce” may also be inferred from evidence of gross overpayment for any legitimate professional services. *United States v. Rogan*, 459 F. Supp. 2d 692, 716 (N.D. Ill. 2006), *aff’d* 517 F.3d 449 (7th Cir. 2008). “Payment exceeding fair market value is in effect deemed payment for referrals." *Am. Lith. Soc. v. Thompson*, 215 F. Supp. 2d 23, 27 (D.D.C. 2002).

114. The Office of Inspector General of the Department of Health & Human Services (“OIG-HHS) has warned providers and suppliers that the provision of “anything of value” puts them on notice to examine whether the relationship violates the AKS; specifically,

> the manufacturer should examine whether it is providing a valuable tangible benefit to the physician with the intent to induce or reward referrals. For example, if goods or services provided by the manufacturer eliminate an expense that the physician would have otherwise incurred (i.e., have independent value to the

> physician), or if items or services are sold to a physician at less than their fair market value, the arrangement may be problematic if the arrangement is tied directly or indirectly to the generation of federal health care program business for the manufacturer.

OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731, 23737 (May 5, 2003).

115. Claims submitted or caused to be in submitted while in knowing violation of the AKS and Stark Laws are false claims.

B. Medtronic Violated the AKS and Stark Laws.

116. Medtronic employs a variety of methods to offer and pay remuneration to those in a position to influence referrals, including to physicians, physician practitioners and nurses, physician practices and treatment centers, to induce them to refer, recommend, or arrange for the purchase of Medtronic's diabetes products, in violation of the AKS and Stark Statute.

117. The remuneration offered and paid formed an illegal financial relationship with physicians in a position to refer government healthcare patients.

118. As explained in more detail below, this remuneration included:

(1) The provision of "iPro clinics," resulting in:

- free clinical support to enable the physician to bill for professional CGM;
- free clinical support to enable the physician to bill for professional services in conjunction with ordering the pump;
- free infrastructure for the practice -- being the "business consultant" to enable increased billing with increased Medtronic referrals.

(2) Above fair market value payments for training associated with every pump order:

- at higher rates than Medicare would pay;
- for more services than actually provided.

(3) Other free services, supplies and incentives, such as:

- free services in the form of a nurse acting as diabetes clinical manager for the practice or center;
- free supplies, such as free iPro devices; and
- free lunches, dinners, or "VIP" trips.

119. Because Stark mandates that the existence of these prohibited financial arrangements bars the submission of any claims for patients referred by the incentivized providers, all resulting claims from these relationships are in violation of a material condition of payment and are false.

120. Because the remuneration identified above was paid with the purpose of inducing the resulting referrals in violation of the AKS, the resulting claims are in violation of a material condition of payment of government healthcare programs and are false.

1. iPRO CLINICS.

a. Description of Remuneration.

121. Medtronic's sales strategy was focused on ways to expand use of insulin pumps into new markets. Pumps were designed and approved for use by patients with Type 1 diabetes. Government healthcare programs have only covered its use for Type 1 diabetics since 1999, and only slightly expanded that coverage in 2001 to include a subset of Type 2 patients whose insulin-dependency mimics that of Type 1. However, because Type 1 diabetes results from genetic predisposition rather than behavioral patterns, the Type 1 market is both small and consistent. Medtronic knew that the growth market for diabetes was for Type 2 patients, many of whom are government healthcare beneficiaries. Thus, Medtronic's marketing tactics focused on ways to

incentivize physicians to order pumps for Type 2 patients who were receiving insulin by injection.

122. Starting in 2008, Medtronic rolled out “iPro clinics” as a national strategy to grow new pump sales, shortly after the FDA approved the iPro for sale to physicians.

123. The iPro is Medtronic’s professional Continuous Glucose Monitoring (“CGM”) device. It uses a sensor inserted under the skin, which continually monitors and measures glucose levels in the bloodstream. The device stores the data so that it can later be downloaded to the physician's computer for evaluation.

124. An iPro patient is fitted with the subcutaneous device in the physician’s office, and wears the device for several days in order to develop a glucose profile. The data are downloaded and reviewed to develop treatment recommendations based on the patterns they reveal.

125. For this service, the physician bills government healthcare and other insurers for the startup, removal, download and technical training related to the device under CPT Code 95250, and the interpretation of the data from the professional GCM under CPT code 95251. Physicians may also bill for office visits before and after the iPro clinics as “Evaluation & Management” (“E&M”) under CPT Codes 99212-99215. If a pump is ordered for the patient, the physician can bill for additional office visits, as well as for training of the patient on the pump.

126. The “iPro clinic,” also called “CGM (or CGMS) clinic,” refers to Medtronic’s practice of scheduling time in a physician’s office for Medtronic personnel to fit the physician’s diabetes patients with the Medtronic iPro CGM device for the ostensible purpose of evaluating their current diabetes management and making improvements.

In these iPro clinics, Medtronic sales personnel, including Mr. Witkin, were expected to perform the actual insertion of the iPro device under the skin of the physician's patient, with no medical personnel present in the room.

127. The true purpose of the iPro clinic was a *quid pro quo.* Medtronic provides physician's offices with free services, including the services of Medtronic employees to run the iPro clinics, knowing that the doctors will bill government healthcare programs for these services. In exchange, providers cooperate with the sales representatives to transform iPro visits into new pump orders.

128. Medtronic Vice President of Sales Mike Gill made iPro clinics the top priority and "deliverable" (*i.e.*, mandatory action) for the sales force. As explained at the 2008 National Sales Meeting, in a presentation entitled "Professional CGM Clinics," the road to a successful iPro clinic was to "[f]ocus on the goal → NPNP" (New Patient, New Pump). Medtronic instructed its sales force to "Execute on iPro Clinics & we will exceed our NPT [New Pump Therapy] goals."

129. At that time, in 2008, each sales representative was required to conduct four iPro clinics, with four MDI patients per clinic, each month. This strategy was enormously successful, and so this requirement was increased in 2011 to five iPro clinics with four MDI patients every month.

130. Medtronic's national sales materials state that "CGM [iPro] is a revenue opportunity for HCPs [Health care practitioners] … Make Sure Your HCPs Know This!"

131. Medtronic delivered this message through use of an "Economic Model" which was developed for each physician or practice. To use the Model, Medtronic sales personnel were provided actual numbers of the practice's diabetes Type 2 patients and

their payor mix. The patient numbers were entered into an interactive computer program, called a “Reimbursement Tool,” and used to demonstrate the profit which the physician could make by allowing Medtronic personnel to perform iPro clinics at the physician’s office. The Model also shows the profit which could be gained by converting patients to Medtronic pumps.

132. In order to complete the Model, sales representatives fill out an “Account Profile Form” for every practice, compiling the underlying information to be entered into the tool, among other things, the number of Type 1 and Type 2 insulin taking patients, and the Medicare mix of the practice.

133. Thus, for every targeted provider, Medtronic instructed its sales representatives to track the percentage of the provider's patients who are beneficiaries of government healthcare programs.

134. Medtronic sales representatives had the “Reimbursement Tool,” on their iPad or computer for the purpose of modeling the revenue numbers generated from the physician’s billing for CPT codes associated with use of the iPro and with converting the iPro session into a pump order.

135. In order to run the Tool, the representative entered variables about the provider’s practice, including the area of the country of the practice (because billing rates vary by region), the number of insulin-dependent patients seen per week, the percentage of patients on Medicare (because Medicare reimburses at a different rate than private insurance), and the start-up costs that may be involved (such as purchase of the professional GCM device). When these and other variables are entered, the Tool demonstrates the billing opportunities for the provider for (1) the use of professional

GCM ("iPro") on diabetic patients; and (2) the additional billing opportunities available if a pump is ordered for each patient who goes through the iPro process.

136. For example, a snapshot of the Summary page for the Model for Dr. Krishnamurthy located in Salem, Oregon, reflects that, based on a Medicare mix of 40% and in anticipation of 16 iPro patients per month, with 4 of those patients converted to a pump order, Dr. Krishnamurthy would receive an additional $5,874 per month to her practice from Medicare:

Medtronic

Medtronic Diabetes Economic Summary

Monthly Summary	Current Protocol(s)	
	Medicare[1,2,4]	Private[3]
Estimated Pump Therapy Reimbursement Per Month	$ 1,430	$ 2,144
Estimated CGM Therapy Reimbursement Per Month	$ 4,445	$ 6,667
Estimated Combined Reimbursement Per Month	**$ 5,874**	**$ 8,811**

Annual Summary		
	Medicare[1,2,4]	Private[3]
Estimated Pump Therapy Reimbursement Per Year	$ 17,155	$ 25,732
Estimated CGM Therapy Reimbursement Per Year	$ 53,336	$ 80,004
Estimated Combined Reimbursement Per Year	**$ 70,490**	**$ 105,736**

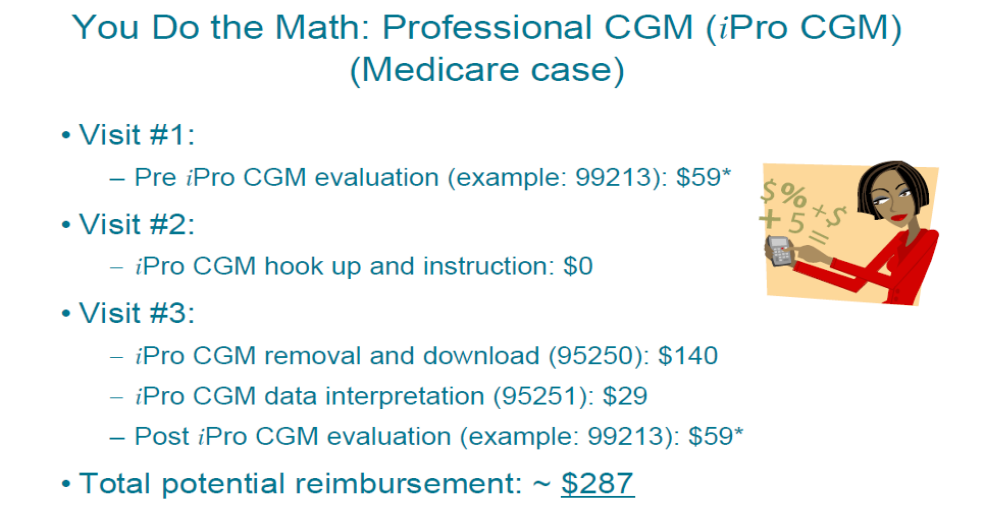
137. Newer iterations of the Tool allow the sales representative to show a provider his or her "Practice Potential" associated with performance of additional procedures. After entering the information noted above, the Tool now shows the provider three options which show that adding "additional procedures" generates additional profit. Each Option shows the incremental revenues with additional orders.

The provider is then asked to choose an option so that he can start ordering Medtronic products and generating revenue.

138. Medtronic calls this model "[t]he Economic Stimulus Package for your Health Care Providers." A Medtronic training PowerPoint instructs sales representatives to first "Assess[ ] the Account" by getting to know the economics of the office and understanding "who has a stake in the profitability or liability of the practice." Medtronic sales reps were trained that "[t]he ultimate decision maker is not always the physician- don't assume."

139. Conversion of a Type 2 patient to the pump affords substantial billing opportunities. When a provider orders iPro for a patient, Medtronic offers to do all the work—to include the medical procedures involved in inserting and removing the device into the patient's body—while the provider is able to bill for the startup, insertion, and removal of the device; the download and interpretation of the data; and office visits before and after the patient's iPro clinic session. This yields a total reimbursement of $287 per patient with little effort by the physician or his or her staff, meaning that each four-patient iPro clinic results in reimbursement to the physician of more than $1,100.

140. In Medtronic's words, "You do the Math:"



141. If the iPro opportunity is converted to the sale of a pump, there are additional billing opportunities. In that case, the provider could bill for one pre-visit and three post-visits under E&M codes, as well as for educational training (DSMT) for the patient, if the practice was a certified DSMT provider. As identified in a 2009 PowerPoint entitled "iProTM Reimbursement & Impact to Your Territory Practices," – "Tips from the Top" (authored by a Corporate Account Manager), the conversion of an iPro patient to the pump could result in more than a "~$500 reimbursement opp. per pt." for the healthcare provider.[5]

142. The driving force behind using the Economic Model to market to doctors is conversion of Type 2 patients to insulin pumps. The iPro device is used to induce physicians to put the sales representatives in direct contact with the patients. Medtronic calls this practice (of leveraging the use of iPro's into pump sales), the "CGM Continuum." Under this strategy, sales representatives were to convince providers, through incentives and otherwise, to set up patients who are on conventional therapy (such as MDI (injections) and orals) on an iPro, and then convert those patients into pump users. The sales representatives were directed to establish themselves as part of the "infrastructure" of a provider's practice or center, and run clinics at the provider's location in order to provide free assistance to the practice and have direct access to patients to further influence the request for pump therapy. (Medtronic PowerPoint, "The CGM Continuum").

[5] Medtronic also taught the provider how to bill these codes so they could maximize reimbursement. Medtronic also instructed the provider to bill the E&M code and the GCM code with a modifier to indicate that the services were provided in one day.

143. By allowing Medtronic personnel to perform "iPro clinics" in their offices, providers gained access to an array of benefits in addition to increased billing. Medtronic provided its sales representatives as "consultants" to the office to assist with or perform the startup, removal and download of data which the physician billed as a professional service. Medtronic routinely offered loaner equipment (and disposable sensors) to reduce the physicians' start-up costs. Medtronic also offered the services of a Medtronic-paid nurse to act as a clinical manager, and offered to pay personnel at the provider's office to provide the pump training. Medtronic also offered other incentives, such as lunches, dinners, and paid trips to the corporate offices to meet Medtronic executives and learn about Medtronic's products.

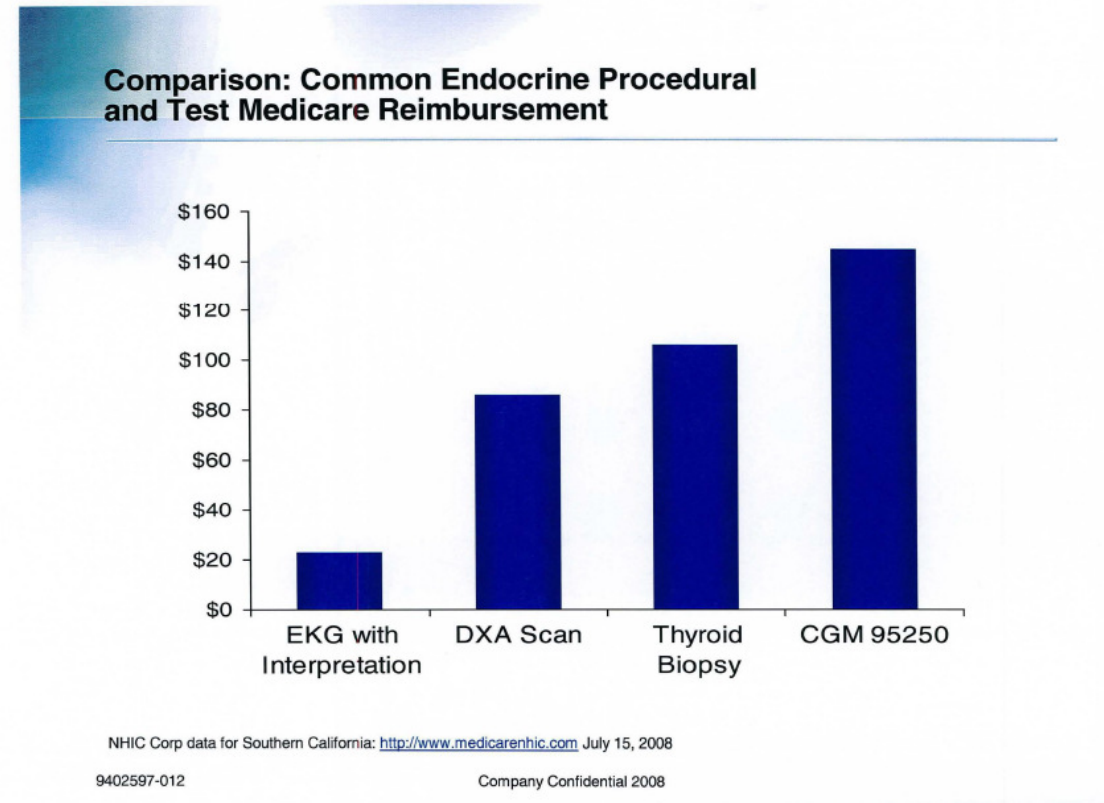
144. As illustrated in Medtronic training material, "iPro Step by Step," Medtronic directs its sales representatives to perform a range of free services, such as "courtesy sensings," that provide value to the provider, including:

Perform Courtesy Sensings:
•...at the MD's office
• Talk to patient about CSII
• Get insurance information, signed AOB
• Call patient next day
• Fax LMN
• Retrieve, Download, Review tracings with MD
• MD and patient should expect to talk about the PRT at next appointment

145. There is no question that these free services provide value to the targeted providers. As part of the "CGM continuum," sales representatives are ordered to "Clarify the available Medtronic Support" combined with the "attractive reimbursement" available to the provider.

146. Medtronic demonstrates to providers that the billing opportunities available from running iPro clinics with Medtronic, and from generating Medtronic pump orders

(under CPT codes 95250 alone) are greater than other procedures that may be performed:



147. In an August 10, 2009 email titled "ROI," a sales representative showed that, at Mary Bridge Children's Hospital, Medtronic personnel were able to assist the staff "to generate enough RVU's [the Relative Value Unit used to calculate physician compensation] to add another FTE" (full-time employee)." Thus, "[h]aving tools like iPro allow us to be true consultants to the office/clinic." (August 10, 2009 Email, Subject: ROI).

148. Mr. Witkin was directed by his District Manager (DM), Mike Ware, to "become part of the office on a weekly, or bi-weekly basis." "The WIFM (what's in it for me) for the doctor's office . . . . We free up office staff." (Email from Relator to Mr. Ware dated October 14, 2010).

149. Medtronic also used its "iPro Clinic" arrangement to gain one-on-one access to MDI patients. Mr. Witkin was instructed that one-on-one time with patients was an important component of the program. Medtronic knew that if it could get its sales representatives alone in the doctor's office with a Multiple Daily Injection patient during the iPro clinic, the likelihood of making a pump sale increased substantially. This is particularly true for patients who are Medicare beneficiaries, because of financial differences in the reimbursement of insulin for injection and insulin for pump infusion. Medicare patients on MDI must pay for their multiple daily insulin doses out of pocket or through their Medicare Part D prescription drug plan, which is necessarily subject to the "Donut Hole" of Part D. Medtronic personnel were instructed to make sure that Medicare patients understood that if they converted to the pump, Medicare Part B covers the cost of the pump device, the pump accessories, *and the insulin* (subject only to patient co-pay). Thus, the iPro clinics were used by sales representatives to persuade Medicare beneficiaries who used Multiple Daily Injections of insulin to request a pump from their physician.

150. In a one-on-one situation, Medtronic sales representatives would "interpret" the results of the continuous glucose monitoring as evidence that the patient needs an insulin pump, whether or not the patient truly needs a pump.[6] Once the patient was receptive to use of the pump, Medtronic would go ahead and fill out the supporting documents for a pump order, for government healthcare and other insurers, and submit them pre-filled to the physician.

[6] Continuous glucose monitoring inevitably shows fluctuations in the glucose levels of the patient and "excursions," *i.e.*, readings above and below safe glucose levels. Medtronic sales representatives are trained to "interpret" CGM data in a manner that raised fears in the patients' minds and show the provider the purported need for pump therapy.

151. Additionally, Medtronic influences the patients, as well as the providers, with as many incentives as possible. Medtronic also offers patients free supplies and waivers of co-pays, in order to induce them to request the pump. Medtronic also falsely represents to patients and providers that the use of the glucose sensor component of the iPro can be stretched to seven (7) days. Medtronic's sensor has been approved for a three day maximum length of use approved by the FDA, and there is a lack of safety and efficacy evidence to using it for longer periods. However, Medicare patients have to pay for that component out of pocket, so Medtronic regularly promotes longer off-label use of its sensors to incentivize patients to agree to pump therapy. Medtronic induces this off-label use of the sensor by misrepresenting to patients that it is safe and effective, and misrepresenting that it expects approval from the FDA for an expanded indication to 6 days. Medtronic fails to tell patients of the lack of safety and efficacy evidence, and fails to tell them that extended use can lead to infections at the insertion site. These misrepresentations and inducements harm patients and reflect the extent to which Medtronic goes to secure a sale.

152. Medtronic managers are candid about the requirement that sales representatives interact with patients during iPro clinics whenever possible, in order to create an "Opp." An "Opp" in Medtronic parlance was a realized opportunity to sell an insulin pump to the patient, in which the patient has agreed to allow Medtronic to fill out the underlying claims documentation (such as a health questionnaire, an Authorization of Benefits) and have a draft letter of medical necessity sent to their provider. Medtronic managers knew that without Medtronic's involvement, the physicians will simply use the information gained from the continuous glucose monitoring device to adjust the patient's

current MDI regimen, which is the standard of care for Type 2 patients.

153. In a January 2, 2009 email, Pacific Northwest District Manager Travis Allen directed his sales representatives this way:

> Put yourself in each of these [iPro] clinics at each start if possible. Ensure they do their starts on established days so you can be there. If they do the tracings alone, they will simply adjust the current MDI regimen. ***If you are there, you'll get Opps.***

(emphasis supplied)

154. One reason the iPro scheme is so successful is that Medtronic personnel become part of the infrastructure of the provider's office. When Medtronic's sales representatives run the clinics and handle the various procedures, the patients view the representative more like a trusted medical professional. This gives the sales representatives enhanced credibility when they present all of the reasons why the patient would benefit from going on pump therapy. Medtronic exploited this trust to convert the "Opps" into sales.

155. Medtronic's practice of having the sales representative become the trusted medical professional in the patient's eyes is particularly abhorrent, and illustrative of its true purpose. iPro sensor insertions are medical procedures. The person inserting the device must plunge a large-bore needle into specific insertion points, often the upper pubis or upper buttocks of the patient. Not only are sales representatives not licensed to perform these procedures, they are ill-equipped to handle any potential complications (such as excessive bleeding or a patient fainting). Patients are not told that the person inserting the device into their body is not medically trained, not an employee of their doctor, and not licensed. Nor are they told that the entire effort is part of a marketing ploy.

156. When Relator first began conducting iPro clinics in doctors' offices in 2008, he was accompanied by a Medtronic Diabetes Clinical Manager ("DCM") – a Registered Nurse employed by Medtronic – who would handle all medical aspects of the procedure, including insertion of the sensor device under the patient's skin. While the corporate directive was for sales representatives to handle the procedure on their own, Relator was uncomfortable with the practice and used a Medtronic nurse. In July 2010, his District Manager Mike Ware became aware of this and insisted that Relator handle the iPro procedure alone, without the assistance of an RN. Medtronic wanted the sales representatives, trained in selling pumps, to be the main point of contact with the patients.

157. In its National Sales Meetings in 2008, Medtronic had sales representatives practice inserting sensors into each other in order to be prepared to have one-and on-contact with the patients. Sales representatives that handled the iPro clinics by themselves, without the assistance of even a Medtronic nurse, were commended by Medtronic management. Their practices were held out as "Best Practices." One such sales representative was Kendall Cook, a Territory Manager in Portland, Oregon. Mr. Cook was featured at a District-wide meeting in January 2011, where he gave a presentation to the group on his "best practices." At that meeting, Mr. Cook stated that he handles the iPro clinics without a DCM present. One of his main accounts for iPro clinics is Adventist Diabetes Center in Portland, Oregon. January 7, 2011 Email from Mike Ware, attaching Account Profile, and other documents; Partnership PowerPoint Presentation.

158. Whether through the sales representative or a nurse, Medtronic's iPro

clinics provide substantial profit to providers.

159. In the words of Relator's District Manager, the Economic Model offered by Medtronic "allows [Medtronic] to be Business Consultants to [their] accounts to help them achieve superior outcomes for their patients and understand the reimbursement opportunities." February 14, 2011 Email from DM Ware. Medtronic is expected to be a part of the "infrastructure" of the accounts through iPro and the Economic Model. October 15, 2009 Email from Pacific Northwest DM Allen.

160. During the iPro clinic sessions that Medtronic schedules with the provider's patients, Medtronic personnel perform all or part of the pre and post visit work, including the insertions and data download and interpretation. The value to the physician of these services is substantial. The services billed by the physician include CPT code 95250 for the CGM sensor placement, hook-up, calibration of monitor, patient training, removal of sensor, and printout of recording; CPT Code 95251 for the associated interpretation and report; and the office visit CPT codes 99212–99215. These CPT codes are paid under Medicare's Physician Fee Schedule (PFS), and those payment amounts are calculated based on relative value units (RVU's) assigned to the specific physician service. 68 Fed. Reg. 63190 (Nov. 7, 2003). The PFS amount is intended to compensate physicians for, among other things, the time and expense it takes to provide services to their patients (valued by RVU). *Id.;* American Medical Association, Medicare RBRVS: The Physician's Guide 2012, at 13. With the exception of Code 95250, every CPT code identified above involves physician services with associated work RVU's for time expended by that physician (which are instead being

provided by Medtronic, in whole or in part).[7]

161. Medtronic thus offers referring physicians a valuable benefit by providing free services, provided by Medtronic's employees, which allow the physician to bill those codes. CPT code 95250 affords reimbursement for the technical component of the two CGM- specific codes, and incorporates RVU's for, among other things, the practice expenses associated with that service. RVU's associated with every CPT code can be found in a public database maintained by the American Medical Association. *E.g.*, https://ocm.ama-assn.org/OCM/DataManager/GeneralInformation.do?code=95251&locality=37).

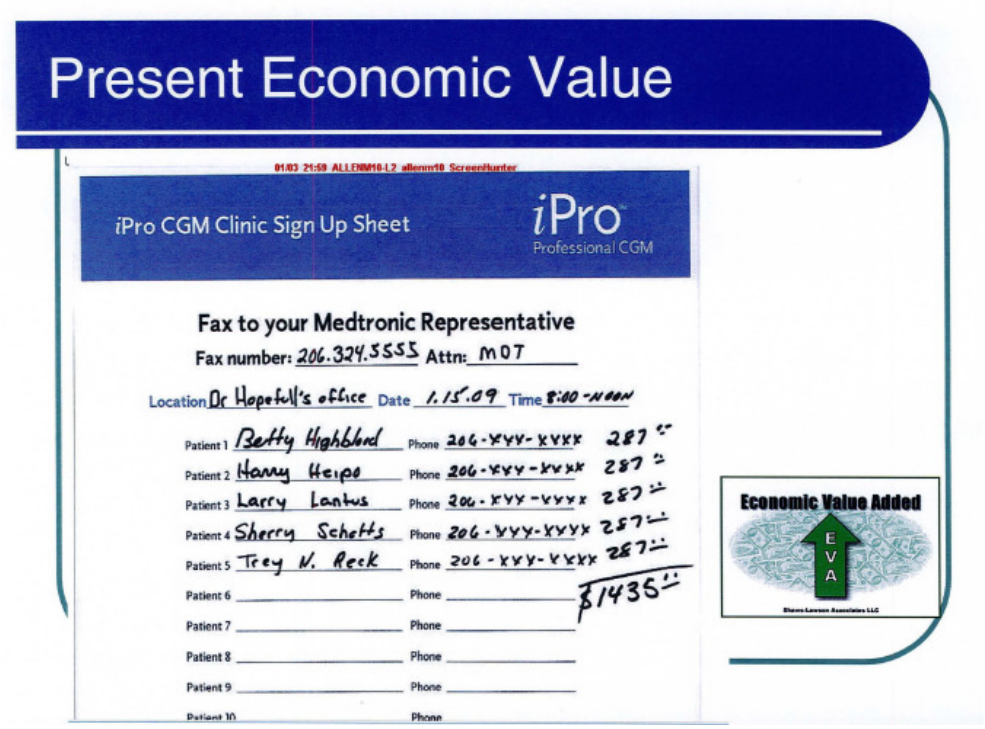
162. In addition to free services provided by Medtronic personnel, the iPro clinic thus also gave the provider substantial revenue opportunities, in the form of professional services billing, at little to no extra effort.

b. Intent to Induce Referrals.

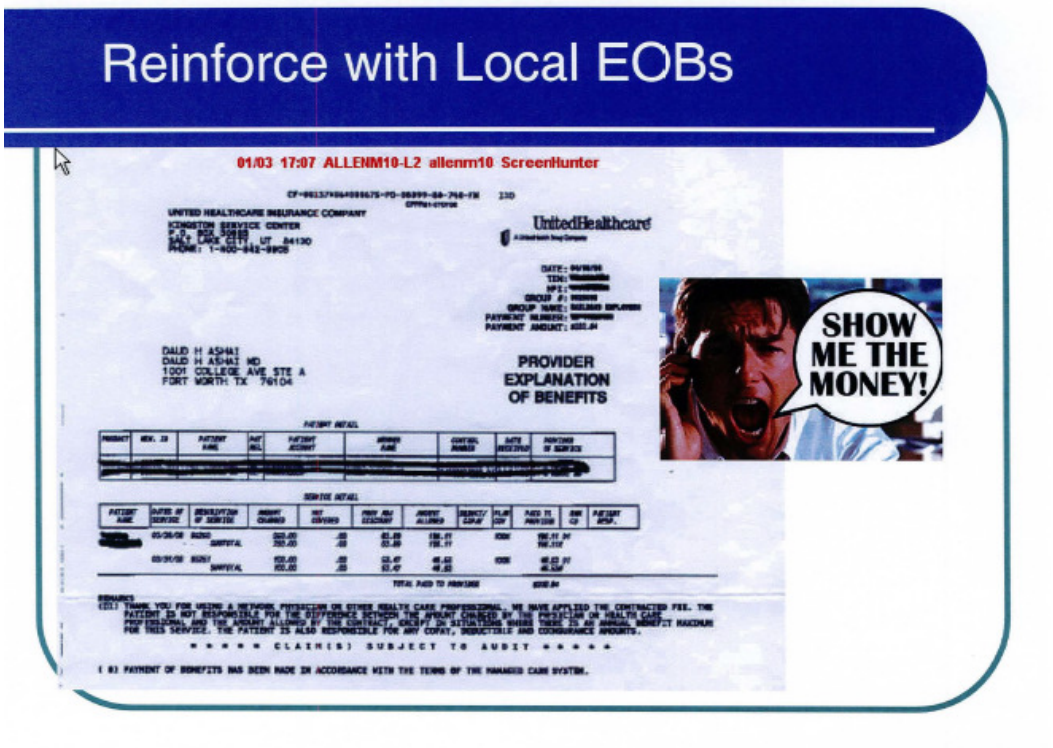
163. All remuneration was provided by Defendants with a purpose of inducing referrals of government healthcare business.

164. That purpose is explicitly illustrated in the "Step by Step" training manual for iPro Clinics, where Medtronic directs its sales representatives to "Present Economic Value" to providers through iPro Clinics:

[7] Medtronic is well aware of this, including how RVU's may be used in a hospital setting to determine a physician's compensation. In an August 11, 2009 email from the West Region Sales Director DiGiulio to his sales reports, he states, "For anyone that has key accounts in a hospital setting, the providers are usually compensated based on RVUs (relative value units). RVUs are a measure of "productivity" or potential income for the hospital. This includes E&M codes, G codes and procedure codes (95250/1). Many accounts in the hospital setting are cutting back because of a lack of profitability. Think about the power of the CGM Continuum (including reimbursement opportunities) and how valuable our partnership can be with these accounts (particularly competitive accounts)."

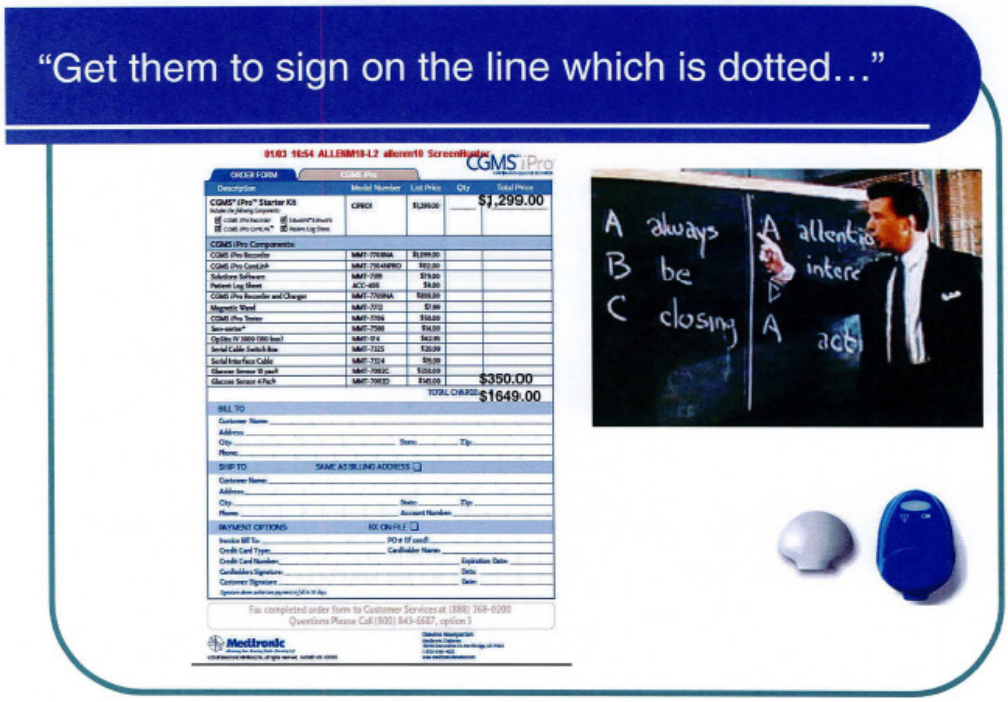


or, as the Paid Claim statements (EOB's) reflect, "Show Me The Money!"

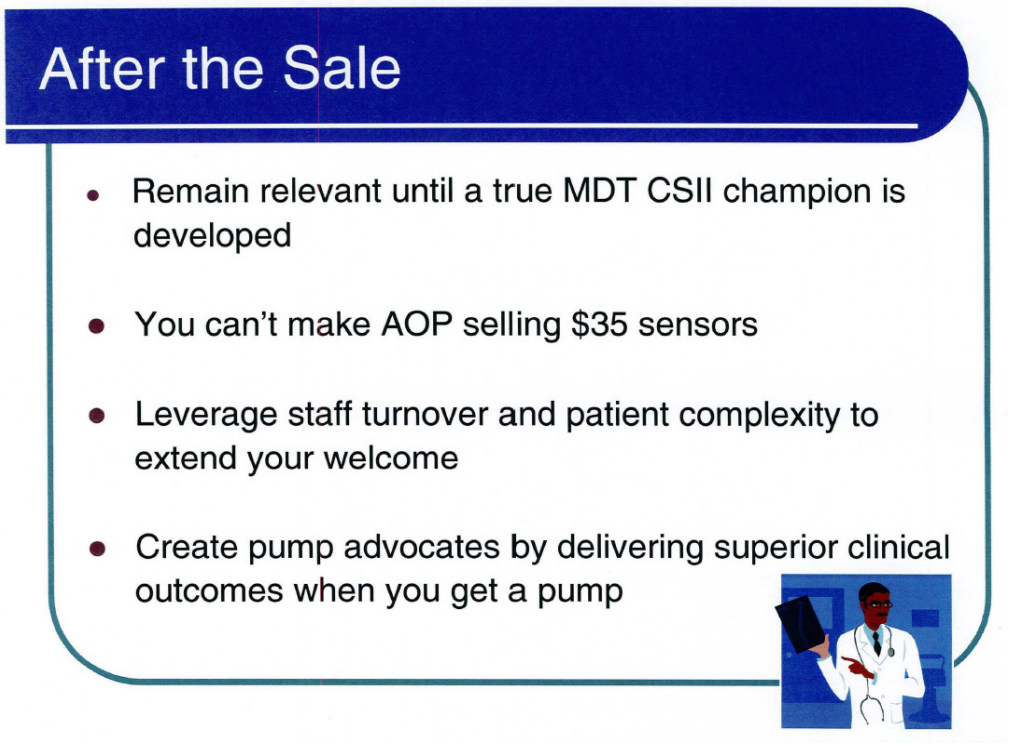


165. These incentives would then "Get them to Sign in the Line Which is

Dotted," the Medtronic order form:



166. "After the sale," the Medtronic representative's job was to "Remain relevant until a true MDT CSII [pump] champion is developed."



167. Medtronic's explicit message to its national sales force was that the goal of iPro clinics was getting new patient orders for the pump ("[f]ocus on the goal → NPNP", 2008 National Sales Meeting Presentation regarding iPro Clinics).[8]

168. In Medtronic's "Train the Trainer" Binder, the purpose of the iPro Economic Model is clearly spelled out: "iPro →pump finder →NPNP." (Connect the Dots Program Implementation Power Point – Phase 4 Coaching). A November 2010 communication to the U.S. Sales Team specifies "iPro is the pump finder – more iPro clinics lead to more NPNP!"

169. The sales force was told to reinforce the economic benefit of iPro clinics with the results of other claims paid to providers (EOB forms) to gain the "economic buy in" of targeted providers for pump orders. (iPro Step by Step PPT at Slide 1).

[8] And, specifically, the goal was to convert new patients (previously on daily injections) to use of a Medtronic pump. (2009 sales PowerPoint, "Key Takeaways: Make sure you set the precedence early so you aren't getting pumpers coming to your iPro clinic").

170. As stated by Relator's District Manager in a 2010 Field Coaching Report, "iPro Clinics are the foundation of our business to deliver NPT [new patients to pump therapy]." (October 25, 2010 FY11 TM/AM Field Coaching Report).

171. "iPro NPNP"[new patient new pumper] was the "magic elixir" for the Medtronic sales team. (October 15, 2009 Email from Pacific Northwest District Manager).

172. The link between the "revenue opportunity" for providers and the pump orders is direct: Medtronic's Economic Model demonstrates to every provider how the conversion of an iPro session to a pump sale results in additional revenues to the doctor and specifically how those revenues correlate to the number of government healthcare beneficiaries in the provider's patient base.

173. The iPro Model was extraordinarily successful in generating new pump sales for Medtronic, and became a driving force for Medtronic to increase sales.

174. A Medtronic sales and marketing report, dated February 2011, reflects that "iPro clinics generated over 40% of all new pump sales." (February 11, 2011 Monthly Sales & Marketing Call PowerPoint). In FY 2011, Medtronic's sales goal was to sell 81,000 pumps. (FY11 MMSales Dashboard).

175. Medtronic was well aware of, and tracked the link between its iPro Economic Model and sales. In a marketing campaign launched in FY 2010, it states: "In accounts where iPro is used consistently, a patient is nearly 2.5 times more likely to get started on insulin pump therapy vs. those accounts that use iPro intermittently or not at all." (PowerPoint, The LOOP Plan of Action).

176. The successes of this Model were well-heralded by Medtronic. By way of

example, according to a Medtronic marketing brochure, Dr. Thomas Blevens in Austin, Texas owns 30 iPro devices and conducts three iPro clinics a week, each with six patients. Over the course of a year, that would generate an estimated $200,000 for Dr. Blevens. (May 2009 Medical Economics article, "Set up Your Practice for Success"). Another heavy user of iPro clinics is Dr. Brian Berelowitz, an endocrinologist in Las Vegas, Nevada. According to a March 29, 2010 email from a Medtronic representative in his area, his office "performs between ten and fifteen iPros per week."

177. A February 2009 email from District Manager Allen emphasized to the sales team that one of the sales representatives had "position[ed] herself in a place to establish a pump champion" by running multiple iPro clinics with as many as 20 iPros for the Colville Indian Tribe.

178. The purpose of the remuneration offered by the iPro clinic model was to induce pump sales and incentivize a provider to be a "pump champion" and order Medtronic pump therapy for all his or her diabetic patients.

2. Above Fair Market Value Payments for Training.

a. Description of Remuneration.

179. Another form of remuneration offered and paid by Medtronic is above fair-market-value ("FMV") payments to train diabetes patients on the use of Medtronic insulin pumps.

180. These payments are intended to and do induce physicians and others to recommend Medtronic insulin pumps and supplies.

181. Medtronic's sales of insulin pumps consist of (1) sales to new patients and (2) sales of replacement models or upgrades to existing patients.

182. Medicare Part B covers diabetes self-management training services ("DSMT") for a beneficiary who is initially using the pump, and for follow-up training in subsequent calendar years, if "the treating physician or treating qualified non-physician practitioner who is managing the beneficiary's diabetic condition [ ] certify[ies] that such services are needed." Medicare Benefit Policy Manual (MBPM) § 300 (July 21, 2007). DSMT must be provided by an accredited DSMT program and billed by a certified provider who has entered into a supplier agreement to bill federal programs. *Id.* at § 300.2.

183. Leveraging on the fact that the Medicare reimbursement for this training was low, Medtronic offered to pay providers and educators at their practices for providing the training at more lucrative rates and without regard to the time actually needed (and spent) in rendering the training. These payments became an extra bucket into which to funnel incentives.

184. During the time that Relator worked for Medtronic, the company accommodated these payments through contracts with those in a position to refer patients, including individual providers, doctors' offices, and diabetes centers (often through contracts called "Center Contracts"). Medtronic would encourage individual providers and members of their staff to become Certified Pump Trainers ("CPT") in order to pay them to train patients on the use of Medtronic's insulin pumps, both new pumps as well as replacement or upgrade pumps. A CPT is typically a Registered Nurse or Registered Dietician that has received further training to become a Certified Diabetes Educator ("CDE").

185. Medtronic's contracts with its diabetes trainers provided for the following

payments:

a. For new patients, Medtronic paid $50 an hour for up to two hours of "pre-pump" training; $225 for pump "start-up" training (paid as a flat rate, no minimum time required); and $50 an hour for up to two hours of post start-up training, for a total of $425.

b. For current pump users purchasing a replacement or upgrade model, Medtronic paid $225 for pump "start-up" training (paid as a flat rate); and $50 an hour for up to two hours of "follow-up" training," for a total of $325. If the replacement or upgrade was provided at Medtronic's expense (such as an in-warranty malfunction or an upgrade through Pathway, a program in which the beneficiary gets discounted upgrades from Medtronic), Medtronic paid nothing for training.

186. Thus, for initial training, Medtronic paid $425 for approximately 4-6 hours of initial training for new pump wearers (assuming up to 2 hours for the flat rate start up training), and $325 for approximately 2 -4 hours of replacement or upgrade training (assuming, similarly, up to 2 additional hours for the flat rate start-up training). As explained below, however, those services were not actually rendered: initial pump wearers generally receive less than 2 hours of initial training and far less in follow-up training.

187. These payments are above fair market value and are paid to induce and reward doctors and CPTs for recommending Medtronic pumps and referring diabetes patients to Medtronic. These payments are made without regard to whether the services are rendered, and at rates well above the amounts that Medicare covers for pump training.

188. These same services are billed to Medicare under HCPCS codes G0108 (for individual training) or G0109 (for group training). Medicare requires that "[w]ith the exception of 1 hour of individual training, training is usually furnished in a group setting…" MBPM, ch.15, §300.3(A). For any additional individual trainings to be

covered, "the need for individual training must be identified by the physician or non-physician practitioner in the referral." *Id.* § 300.4. Medicare pays for not more than 10 hours of initial training and 2 hours of follow-up training if the follow-up is in a subsequent calendar year. *Id.* § 300.3(B). Payment may only be made for training hours ordered by the physician, and actually rendered and documented, for beneficiaries who have not already had initial or follow-up training. *Id.* § 300.3(A), 300.5.

189. Medicare reimbursement for individual and group training during the relevant time frame was $23.45 and $12.99 per 30 minutes, respectively. In FY 2011, the reimbursement for training was increased to approximately $54.70 and $18.69 per 30 minutes. Thus, under Medicare's conditions of payment for DSMT, the maximum reimbursement for pump training for a Medicare beneficiary for the same time frame contracted by Medtronic would be no more than $176.80 (increased to $296.30 in 2011) for the initial training (assuming one hour of individual training and 5 hours of group training); and $51.96 (increased to $74.76 in 2011) for 2 hours of training for a replacement or upgraded pump (because Medicare will pay no more than 2 hours of follow-up training in the calendar years following a patient's initial training).

190. In reality, new pump beneficiaries almost never need (nor receive) 6 hours of initial training – most patients receive under 2 hours of total initial training, and far less for follow-up training. Because a replacement or an upgrade would only require training on new features (if applicable), existing pump patients need (and receive) little additional training for a replaced or upgraded pump.

191. Medtronic knows that two hours of training for new patients is more than enough time to train the patient on all aspects of the pump and its use and care. At 2

hours, the allowable Medicare reimbursement (even giving the benefit of the doubt for the necessity of at least 1 hour of individual training), would be less than $100 (increased to $184 in 2011). Yet, most trainers paid by Medtronic complete the patient's training in less than two hours and bill Medtronic, at minimum, the $225 "start-up" training.

192. Of note, many patients take advantage of Medtronic's free website training even before they see a trainer and learn virtually everything they need to know about the pump before their first training session.

193. Medtronic makes no attempt to monitor the time actually spent by diabetes trainers because the point is not to pay them for services rendered but to reward or induce them to recommend Medtronic's products. Some trainers combine the two hours of pre-pump training and the "start-up" training into a single session of less than two hours, and receive $325 from Medtronic. Sometimes the trainers even combine the pre and post-training with the start-up training and bill Medtronic for the full $425 for one session of training. In all of these circumstances, Medtronic's payment is well above the fair market value of the services rendered and constitutes a reward or inducement to the recipient for recommending Medtronic's insulin pump.

194. For many diabetes centers, the training fees literally kept them in business. These centers are normally staffed by RNs and RDs, and they do not have a physician to bill under. Medicare reimburses RNs and RDs for diabetes training under G-Codes that pay a very nominal amount, less than $20 – not enough to pay the center's bills. Medtronic told these diabetes centers that if they found new pump patients for Medtronic, Medtronic would pay for the pump training at above fair market

value rates, $425 per patient. This arrangement allowed many diabetes centers to keep their doors open. Medtronic made clear to them, however, that they would eat what they kill, *i.e.,* that they would need to find the pump patients that Medtronic would pay them to train. This was a powerful financial inducement to these centers to refer pump patients to Medtronic.

195. Even more egregious than the payments for new patient training, however, are Medtronic's payments for "replacement" or "upgrade" pump training.

196. During the time Relator worked for Medtronic, the company paid for replacement pump training even if the patient was put on the same exact pump. Obviously no training is required in those circumstances. Even when the patient receives an upgrade, *i.e.*, a newer model, very little training is needed since the changes in models are relatively minor. Nevertheless, Medtronic still paid doctors' staff and qualified trainers $225 for "start-up" training on replacement or upgrade models, plus $50/hour for two hours of follow up, for a total of $325. Conversely, Medicare would limit this training to approximately $50 (or $75 post 2011) for 2 hours of follow-up training. The purpose of this payment was to reward and induce the recipients to recommend Medtronic's pumps to their patients.

197. Medtronic pitched the "training" fee to doctors as a way to hire an extra PA, RN or CDE. If an office did enough pump trainings during the year, Medtronic's training payments could pay the salary of the new staff person, who would only have to devote a few hours a week to these trainings.

198. In early 2011, Medtronic decided to reign in the payments for replacement pump training. The company decided to stop paying $225 for "start-up" training for

every replacement pump, but left intact the payment for two hours of follow-up training at $50/hour.

b. Intent to Induce Referrals.

199. Medtronic paid people in positions to influence referrals (to include individual providers, physician practices, and diabetes centers) for training. The purpose of these payments was to induce referrals.

200. Medtronic's training payments were above fair market value. Medtronic paid trainers at rates higher than Medicare rates, for amounts of time which were neither necessary nor actually rendered.

201. For example, while most initial pump training was rendered in less than 2 hours, Medtronic paid between $225 and $425 for those services, while the allowable Medicare Fee Schedule for that same amount of time was less than $100 (increased to $184 in 2011).

202. Even though it paid these excessive rates, Medtronic did not monitor nor require the documentation of hours expended by the paid providers or centers. Nor did Medtronic limit the payments to the amount of training actually needed by the patient. Medtronic's practice was to pay any additional training fees requested by the trainers.

203. Medicare pays for no more than two hours of follow-up training for patients in subsequent calendar years, and then only in a group setting, and only if the patient had not previously received initial or follow-up training. Thus, upon the certification of need by a doctor, Medicare would pay $51.96 (increased to $74.76 in 2011) for follow-up training, while Medtronic would pay up to $325 without regard to services needed or expended.

204. Moreover, Medtronic made clear that the payments were tied to new pump orders. Medtronic did not pay for training when the pump order was an in-warranty replacement (which generated no new revenue for Medtronic) or an upgrade under the Pathway program (under which a patient in warranty could upgrade to a new model at a low cost). Yet, Medtronic paid $325 for training when a patient received the exact same upgrade if the upgrade was purchased at the full retail price. (*E.g.,* Feb. 11, 2011 Emails re. Medtronic training payments; Feb. 4, 2011 Medtronic Invoice with check copy).

205. Medtronic marketing documents explicitly link these payments to referrals. In reference to "Cooper Endo" in Cherry Hill, NJ, for example, Medtronic listed as its marketing tactic "money for trainings" and noted "the higher amount paid for trainer is definitely an issue. (August 20, 2009 marketing analyses of targeted providers, key influencers, and marketing tactics).

206. By way of further example, in 2011, when Medtronic tried to reign in pump payments by informing providers that patients purchasing replacement pumps would receive their start-up training by attending a webinar, or being trained by Medtronic over the phone, the Endocrinology Department of the Bend Memorial Clinic in Bend, Oregon ("Bend Clinic"), one of Medtronic's largest customers in Oregon, threatened to stop recommending Medtronic's insulin pumps to its patients.

207. The clinic stated: "For the last four and half years the process has been that our clinic has completed the upgrade teaching for our patients that we manage on Medtronic insulin pumps and our clinic is reimbursed $225 for insulin pump upgrades." The clinic representative then expressed "concern that it [stopping the payment] would

definitely lead us to seriously consider choosing other insulin pumps for our patient population." (Feb. 22, 2011 Emails between Tonya Koopman and Jennifer Minahan, Subject: Upgrade Pump training).

208. Faced with this response, the Medtronic District Clinical Lead agreed to continue the payments:

> I have addressed your concerns with our inside teams and due to how the contract reads now we are going to continue to honor how things have been reimbursed historically for Bend Memorial Clinic. I really appreciate your candid communication regarding this and hope that we can continue to partner with you and your patients.

3. Medtronic's Provision of Other Free Goods and Services.

a. Description of Remuneration.

209. Medtronic also offers and pays other types of remuneration in exchange for the ordering of its products.

210. For example, through its "Nurse in the Office" program, Medtronic provides free nursing services to doctor's offices. Medtronic's purpose in providing these free services is to gain better access to the offices' diabetes patients, and to incentivize physicians to order Medtronic pumps. Medtronic uses this ploy with very competitive accounts or those in which Medtronic only has limited access to the patients.

211. Each sales territory has at least one Medtronic DCM (Diabetes Clinical Manager), who is a licensed nurse or a dietician. The DCM travels around the territory and provides free diabetes health care. In certain target offices, the DCMs will offer to establish set office hours, one or more days a week. For offices that accept this offer, the "nurse in the office" quickly becomes viewed as an extension of the office staff. In

that capacity the DCM gains access to patients and patient records. Medtronic expects its DCMs to provide the Medtronic sales representatives with information about potential pump candidates for sales purposes.

212. Medtronic has hired nurses to work full-time in large accounts in order to take over the diabetes programs in the accounts. For example, Relator is aware of this happening in a large account in Seattle. Medtronic's objective is to capitalize on the access in order to convert more patients to Medtronic's insulin pump. If Medtronic pays a nurse a salary of $65,000, for example, it only takes approximately seven new pump sales (including revenue from the pump, sensors, supplies, and accessories) to pay the nurse's salary.

213. Medtronic also provides remuneration in the form of loaner iPro devices. Medtronic calls these loaners "demo" devices. Medtronic tells the doctors' offices that they can bill for the iPro clinics using the demo devices as long as they own at least one iPro device themselves. Relator's territory had 14 iPro demo devices. Three of these devices were expired, but that did not stop Medtronic from using the devices on patients. The three expired devices came from the corporate office. When the company has expired products, rather than disposing of them, it routinely provides them to the sales representatives to use as demo products. This was the case with the three expired iPro demo's as well as a later corporate shipment of demo insulin pumps and transmitters. The field sales force was not told that the demo units were expired. Providing the sales force with expired demo devices is a reckless and unsafe practice, since it encourages use of expired products on patients.

214. Another avenue of remuneration that Medtronic provided was to offer free

lunch and dinner programs. Each Territory Manager and District Manager had a marketing budget for the purpose of offering incentives to providers. TM's had approximately $25,000/year budgeted for this purpose, and the District Managers had much more. Among other things, sales representatives could use this budget to purchase iPro units and sensors to offer for free to providers and patients.

215. In addition, Medtronic's promotional partners also provided budgets for marketing activities, including for the purpose of offering incentives to providers. For example, Eli Lilly provided Medtronic with a budget for lunches and other promotional offers as part of its alliance with Medtronic to market insulin for use with the pump. Relator was instructed by his District Manager that his Lilly counterpart had $1000 to spend for "collaboration lunches." Relator was directed to utilize these resources with his target providers.

216. Sales representatives were also expected to meet with their "counterpart" at Lilly to "train [them] on iPro messaging, identify targets and plan joint activities." (2010 U.S. Sales Team Communication). Sales representatives were expected to coordinate with their counterparts to plan dinner programs for providers. By the end of September 2010, an email reflects that the joint Lilly program had resulted in "140 programs completed or scheduled and close to 1000 [providers] who have attended!"

217. Medtronic also offered remuneration with its "Connect the Dots" (CTD) Program. The CTD program began when Medtronic joined forces with Lifescan (Johnson & Johnson) to co-promote the Lifescan blood glucose meter that communicates with Medtronic's pump. Lifescan gave Medtronic marketing dollars to pay for this program as part of a deal to be Medtronic's exclusive glucose meter

provider. Medtronic handed out free Lifescan meters at the clinics (even though this is a prescription product) and when iPro clinic patients received a new pump, it came with a new Lifescan meter. (Connect the Dots program introductory letters; CTD program agreement and account profiles; award letters; 2010 Interactive Business Plan & CTD Web Site Tools PowerPoint). For accounts which did not agree to set up an iPro clinic, Medtronic gave another try via the Connect the Dots program.

218. If a provider signed up for the CTD program, he or she automatically received "an iPro demonstration kit, a 4-pack of sensors, a diabetes textbook, and the opportunity to submit a Professional CGM case study for publication in a peer reviewed journal." (CTD program Introductory Letter). Once part of the program, the provider and members of the practice staff were offered free travel and accommodations to attend iPro symposiums at luxury venues.

219. The CTD program co-ventured with Lifescan ended when that partnership ended in 2012, but aspects of its free incentives continued.

220. Medtronic offered these promotional incentives with the purpose of inducing orders of its products.

b. Intent to Induce Referrals.

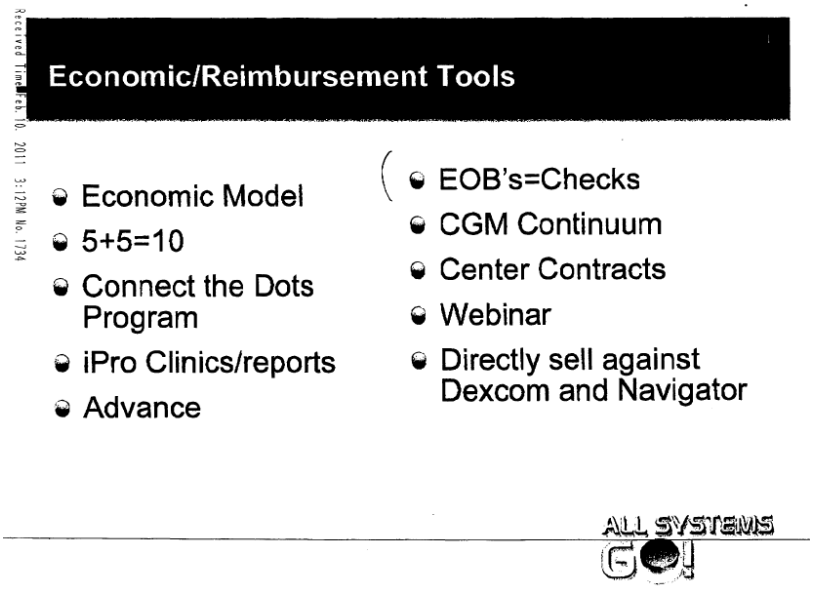
221. Medtronic offers its range of free incentives with the purpose of inducing increasing referrals of pump orders.

222. Medtronic refers to these multiple incentives as its "Economic Stimulus" package. Each element of the package was not only above fair market value, but explicitly tied to its goal of inducing pump orders.

223. In order to determine what options to offer, Medtronic representatives are

trained to identify the "WIFFM" (What's in it for me) for the physician to order Medtronic Products. (WIFFM for MD PowerPoint at 6).

224. As described in a Medtronic PowerPoint, its "Economic Stimulus Package" had many tools in its arsenal:[9]

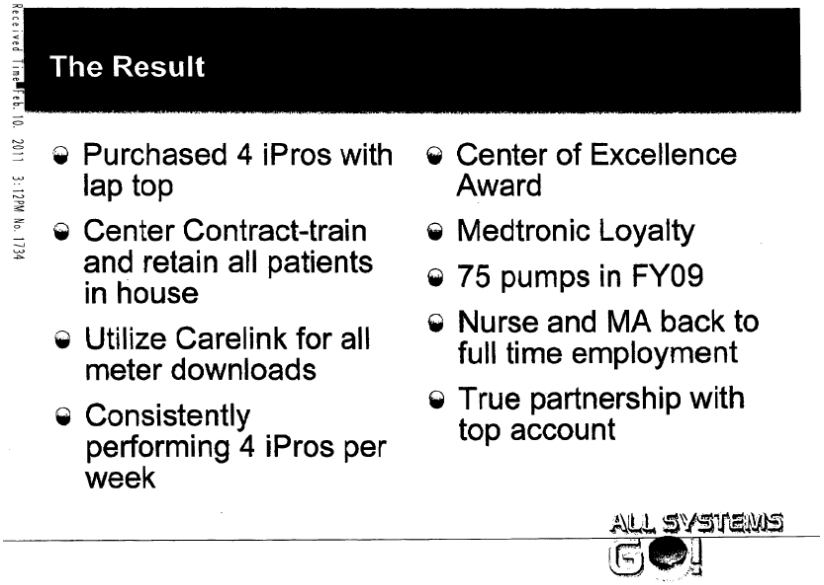


225. That same PowerPoint demonstrated the direct link between Medtronic's Stimulus package and referrals with the success story from the offer of these incentives to a Reno, Nevada, provider, Dr. Caruso. That provider was in economic trouble and was on a spending freeze, cutting back on staff hours, and dealing with the stress of his office staff due to workload. Medtronic representatives met with the practice about Medtronic's Economic Model and the CGM continuum (showing the revenues to be obtained from iPro Clinics and the conversion to pump orders, with Medtronic's free

[9] PowerPoint entitled "Economic Model/Reimbursement-The Economic Stimulus Package for your Health Care Providers" authored by the Sacramento East Territory Manager and Diabetes Clinical Manager. Of note, "Advance" refers to a billing resource offered to providers, which included presentations about how to obtain reimbursement for Professional CGM; "EOB" is an "Explanation of Benefits" form which documents a paid claim (Medtronic used EOB's from Medicare and other insurers to demonstrate to providers the actual revenues to be earned); Dexcom and Navigator [competitor products].

help). They also provided the services of a Medtronic DCM and nurse, and educated the practice's nurse (who ultimately became a certified diabetes educator) and offered a Center Contract for training.

226. The successful "Result" of those incentives was pump orders and Medtronic loyalty:



227. Medtronic well knew these successful results. Medtronic performed Return on Investment (ROI) analyses and tracked attendees of its symposiums and the CTD accounts to determine how these programs impacted the NPT sales. Medtronic saw huge gains in NPT sales in these accounts. By way of example, Relator recalls seeing slides showing the increase in NPT in the 30 to 40% range among attendees of the Las Vegas iPro Symposium he attended.

228. Medtronic made clear to its sales force that representatives should use these programs and free incentives to drive sales: In an October 2010 email to the U.S. Sales Team, representatives were instructed to continue to use Connect the Dots to "drive NPNP performance." In a November 29, 2010 email, District Manager Ware

instructed that an effective way to get sales results was to "Leverage[ ] Medical Economics and Lilly Partnership…"

C. Medtronic's AKS and Stark Violations Resulted in False Claims to Government Healthcare Programs.

1. Causal Link to Claims Submitted to Government HealthCare Programs.

229. Compliance with the Stark and AKS laws are a material condition of payment of government healthcare claims.

230. Medtronic is aware of these preconditions. Medtronic's Annual Reports state that "U.S. federal government health care laws apply when we submit a claim on behalf of a U.S. federal health care program beneficiary, or when a customer submits a claim for an item or service that is reimbursed under a U.S. federal government-funded health care program, such as Medicare or Medicaid." Medtronic discloses that the principal federal laws applicable to their reimbursement are the FCA, AKS, and Stark laws, as well as similar state FCA's, anti-kickback, and anti-self-referral and insurance laws. Medtronic 2012 Annual Report at pp. 15-16, 19.

231. At all times material to this action, Medtronic knew that the reasonable and foreseeable consequence of their schemes was the submission of claims to government healthcare programs.

232. If a pump is ordered by a provider, it results in the following claims: (1) claims for the insulin pump and attendant supplies which are submitted by a contractor on behalf of Medtronic; (2) a claim for the insulin filled by a pharmacy upon the physician's prescription; and (3) claims for professional services of the treating physician. Medtronic knew these claims were submitted to government healthcare

programs for every patient it successfully converted to a pump order.

233. First, Medtronic has been at all times material to this action aware that a significant percentage of diabetic patients are insured by government healthcare programs and that, specifically, a large percentage of its targeted providers across the country treat government healthcare beneficiaries.

234. By way of example, the marketing document created on August 20, 2009, reflects that Dr. Kelly Flesner in Tulsa, Oklahoma "has a large elderly/medicare population and wants a color screen, larger fonts, etc.; and that Dr. Joellen Habas in Cherokee North Carolina is a "very large opportunity because (sic) up until now they have had no pump coverage [and] large % have medicare/medicaid also."

235. Second, Medtronic tracks the government payor information for its accounts through its Account Profile Forms, used for its Economic Modeling for targeted providers, and is aware that its arrangements result in claims to government healthcare beneficiaries.

236. By way of example, Medtronic's Account Profile of the Adventist Diabetes Center revealed that Medicare patients comprised 30% of the practice; the Account Profile of The Dr. Bassett Clinic in Salem, Oregon, revealed a 40% Medicare and 15% Medicaid patient population; the Account Profile of Peace Health of Eugene, Oregon, revealed a 35% Medicare and 20% Medicaid population; and its profile of Institute of Diabetes and Endocrinology revealed 60% of its patient received Medicare coverage and 10% were covered by Medicaid. A training workshop modeling "Economic Outcomes" from Medtronic's business model showed that West Endocrinology Group in Los Angeles, California was 20% Medicare and that Dr. Howard Edelman's

Endocrinology practice in Portland, Maine was 30% Medicare.

237. Medtronic knew its marketing incentives resulted in sales from other government healthcare programs as well. For example, Medtronic conducted iPro clinics for Indian tribes (*see supra* ¶ 177) and ran a special Veterans Administration Issue of its newsletter, *Channel Sales Chronicle*, reflecting "Top Performing Veterans Administration Medical Centers" (VAMCs) for 2010 based on purchases of Medtronic Insulin Pumps. Thus, Medtronic is well aware of the public and private mix of its provider targets, and the fact that government healthcare programs are prominent payors for the patients of its provider targets.

238. Medtronic also regularly collects the Explanation of Benefits ("EOBs") information on paid claims for physician services for diabetic patients, including Medicare and Medicaid patients, as well as Medicare allowable percentages per plan from physicians and/or their office managers. By way of example, Medtronic Field Sales Training Manager Erin Lynch created a presentation entitled "iPro Positioning for success." In it, she instructed sales representatives to conduct a thirty minute once per month office manager consult in which the representative engaged in "EOB Collection/Medicare allowable percentage per plan."

239. Medtronic also compiled the EOB information into an "EOB Rollup," in order to track trends in reimbursement amounts. Specifically, sales representatives in each region would collect EOBs from their accounts and submit or "roll them up" to their District Managers who would track them and in turn "roll them up" to the Regional Managers or managed care providers.

240. Medtronic representatives were required to have "Economic Skills" training

in government healthcare reimbursement in order to determine target practices' economic return for Medicare patients. In Medtronic's Economic Skills training, sales representatives are instructed on how to determine, inter alia, the net reimbursement from Medicare that iPro evaluations and pump therapy would bring into the practice. Medtronic's national "Reimbursement Tool" for modeling the revenue to be gained by targeted providers is based on Medicare reimbursement numbers. Medicare reimbursement rates were carefully tracked and distributed to the entire sales team. (*E.g.*, December 2009 distribution from Medtronic's Senior Director of Reimbursement and Health Affairs; Medtronic Corporate Account Manager Presentation, "iPro Reimbursement & Impact to Your Territory Practices.").

241. Medtronic also regularly provided government healthcare reimbursement information to targeted providers. (*E.g.*, Physician Reimbursement Guide Fact Sheet). Its iPro Professional CGM Practice Guide, targeted to physicians, billing specialists, office managers and other office staff, contains a 30 page section on Reimbursement, including information on government healthcare reimbursement coding and how to fill out the Medicare claim form, the CMS 1500.

242. Medtronic's "CGM Billing and Reimbursement Guide" illustrates for providers that the Medicare CGM reimbursement has a higher rate of reimbursement than other common endocrinology procedures (*see supra* ¶ 146). Medtronic provided handouts to sales representatives at its workshops on how to utilize the CGM Billing Guide to address concerns with accounts when the "main objection is concern of reimbursement. ("Play Big"" workshop).

243. Finally, at all times material to this action, Medtronic has known that

claims to government healthcare programs are the reasonable and foreseeable result of its incentive schemes because Medtronic has prepared the underlying claims documentation for the pump, including government healthcare beneficiaries, and has submitted those documents to a contractor to submit the claim to government health programs.

244. Representative examples of specific claims resulting from these incentive arrangements are in Section I.C.2, below.

245. Submitting or causing the submission of claims to government healthcare programs while in knowing violation of a material condition of payment violates the FCA.

246. Once Medtronic forms a financial relationship with a referral source through the payment of remuneration, Stark provides that no claim can be submitted or cause to be submitted by Medtronic from a referral from that source.

247. Medtronic's remunerative relationships in violation of Stark render any resulting claim noncovered and nonpayable, and in violation of material conditions of payment.

248. Once Medtronic forms a financial relationship with a referral source through the offer of remuneration, and any purpose of that remuneration is to induce referrals, the AKS is violated. The AKS provides that any resulting claims are false claims in violation of the FCA.

249. Lack of medical necessity is not an element of the AKS. Rather, Congress criminalized the conduct in question because it would be an impossible burden for prosecutors to untangle the medical judgment of a healthcare professional after it has been tainted by illegal incentive. *See* legislative history of AKS, H. Rep. 95-393, 95th

Cong., 1st Sess. at 47, *reprinted in*, 1977 U.S.C.C.A.N. 3039, 3050 ("Furnishing excessive services is … difficult to prove and correct. Since the medical needs of a particular patient can be highly judgmental, it is difficult to identify program abuse as a practical manner unless the overutilization is grossly unreasonable.").

250. Moreover, assertions that the physician has exercised "independent medical judgment" do not break the causal chain between Medtronic's incentives and the resulting claims. Not only is this proposition in question when it comes to paying kickbacks with the very purpose of influencing the judgment of the gatekeepers, the physician's role "only breaks the causal connection when it is unforeseeable." *Franklin v. Parke-Davis*, 147 F.Supp. 2d, at *39, 52 (Dist. Mass. 2001).[10]

251. Rather, for the purpose of government healthcare reimbursement, the relevant inquiry is whether the claim or the underlying transaction violated the Stark laws (by the mere existence of a financial relationship with the referral source) or violated the AKS (because any purpose of the remuneration between the parties was to induce referrals).

252. As evidenced by its own careful tracking of the success of its incentives (*see supra* ¶ 174), illustrating that its iPro Clinic model resulted in 40% of its new pump sales), at all times material to this action Medtronic's actions have been a substantial factor in the government healthcare claims resulting from referral sources with which it has a financial relationship.

[10] In *In re: Neurontin Marketing and Sales Practices Litigation*, the First Circuit Court of Appeals affirmed the underlying court's determination that doctor-by-doctor evidence of "influence" by marketing methods is inherently unreliable and that, instead, econometric modeling was sufficient to establish causation. 2013 U.S. App. LEXIS 6793, at *16-17 (1st Cir. Apr. 3, 2013).

253. As alleged above, Medtronic incentivized providers with the purpose of inducing sales.

254. Medtronic also incentives its sales force to execute its national corporate strategies by setting aggressive and constantly increasing compensation-based sales quotas for its sales force, including the number of new patients to the pump (NPT) per month. Failure to meet sales quotas affects your compensation and can result in termination.

255. Thus, claims to government-insured claims are not only the foreseeable, but the intended result of Medtronic's actions.

256. Medtronic's actions to influence the referral source in violation of the AKS and Stark are capable of influencing the Government's decision to pay claims from those referral sources.

257. Defendants' kickback schemes have been occurring since at least 2004 and are on-going.

2. Representative Examples of Prohibited Financial Relationships and Resulting False Claims.

258. Relator worked as a sales representative for Medtronic for seven years. During that time frame, he received many written directives from Medtronic's corporate offices, including through his district and regional manager, regarding the incentives to be offered to targeted providers to induce them to refer business.

259. He also personally observed a number of the financial relationships that were formed with providers as a result of those incentives and is aware that those relationships resulted in increased orders of the Medtronic pump for government healthcare beneficiaries.

260. Relator knows that Medtronic's incentive schemes resulted in claims for government healthcare beneficiaries because it was the sales representative's job to initiate the underlying claims documentation for a pump order.

261. Once the sales representative had contact with a patient, through an iPro clinic session, for example, or through referral from the a practice or diabetes center, the representative would talk with the patient to complete a 4-paged Health Questionnaire which compiled some of the underlying information necessary to submit a claim for the pump. The sales representative would also have the patient sign an "Authorization of Benefits" form which allowed a claim to be filed on his or her behalf.

262. Once that information was obtained, the representative would forward this underlying claims information to a Diabetes Therapy Associate ("DTA"), who would forward it to an insurance representative at the contractor that Medtronic used to process claims (referred to internally as "dealers"). The insurance representative would prepare a draft letter of medical necessity for the physician to sign and would send the pre-filled order with the underlying claims information to the physician.

263. The physician would rely on Medtronic's paperwork to order the pump.

264. While Relator does not have access to the resulting claims submitted by the contractor, or by pharmacies for the prescriptions, he did have access to the underlying claims information for patients of practices that he serviced as part of his job. Relator also had access to Medtronic reports verifying that pumps had been ordered and shipped for listed beneficiaries.

265. Based on his personal knowledge of the financial relationships with targeted providers, practices, and centers, and the claims resulting from those

relationships, Relator and his counsel reviewed all patient information in his possession (including the underlying claims information) to prepare the information provided below.

a. Dr. Priya Krishnamurthy.

266. Dr. Priya Krishnamurthy practices in Salem, Oregon and owns shared office space at the Physicians Building Group. She started her practice in 2010 and was struggling financially. Although an endocrinologist for approximately 15 years, Dr. Krishnamurthy had not used iPro or Medtronic pumps until Medtronic approached her in her new practice. Soon after she arrived in Salem, Relator took her to dinner and presented Medtronic's Economic Model to her and showed her that Medtronic could run the clinic and do the work and she could bill Medicare for four patients each week for iPro devices, using CPT codes 95250, 95251 and 99214. The Economic Model was used to show her that these procedures would result in annual revenue of $53,336 annual dollars to her practice in Medicare, and an additional $80,004 from private payers, based on an approximate 40 percent Medicare mix. Dr. Krishnamurthy and Relator reviewed and discussed the Model several times. Dr. Krishnamurthy eventually chose the option Medtronic hoped: She opened her office to Medtronic-conducted iPro clinics. By October 2010, Medtronic and Dr. Krishnamurthy were regularly scheduling eight patients every two weeks. Dr. Krishnamurthy allowed Medtronic personnel complete access to her patients in order to perform the iPro insertions and removals.

267. DCM Christina Makinson or Relator visited Dr. Krishnamurthy's office at least every Monday. At the end of 2010, Relator informed the physician that she needed to own at least one iPro in order to continue billing the CPT codes. Realizing she would not be able to profit personally from the iPros, Dr. Krishnamurthy indicated

she wanted to stop the iPro procedures until the issue was sorted out. By the beginning of January of 2011, she had purchased two devices, and continued the iPro procedures at a high volume. Rather than only using her own equipment, however, she was continuing to perform several iPro procedures per week and billed for all of the procedures, rather than just the two iPros she owned.

268. Medtronic loaned its own iPro equipment to Dr. Krishnamurthy at no charge, in order to further incentivize her to refer more patients into the clinics (without having to buy additional equipment) and to realize more profit. The free equipment included iPro units, iPro recorders, disposable sensors and use of a mobile color printer. Medtronic and Dr. Krishnamurthy aimed to schedule eight patients every other week for an iPro clinic. Dr. Krishnamurthy billed the CPT codes 95250, 95251 and 99214, which provide reimbursement to include the hook up, download, cost of the sensor and follow up visit, even though Medtronic staff performed each of the services and provided the bulk of the iPro recorders and sensors free of charge. None of her staff, to include Dr. Krishnamurthy, were ever trained to perform the iPro procedures and never performed them. Medtronic assisted Dr. Krishnamurthy in adding tens of thousands of dollars to her income annually, with no significant outlay of expense of time by the physician or practice.

269. In less than a year, Dr. Krishnamurthy prescribed approximately twenty pumps. Further, Relator knows from working with the physician on the practice's Economic Model, that approximately 33 to 40 percent of her practice was comprised of patients who are government-insured. Indeed, she was the only endocrinologist in Salem, Oregon, and took many government-insured patients. Relator attended each

iPro clinic download and knows that many of the patients were government-insured and that many of these opportunities for increased billing resulted in a pump order.

270. By way of example, Relator has an "iPro Tracker" spreadsheet regarding a clinic conducted in Dr. Krishnamurthy's office on October 25, 2010 which included two Medicare beneficiaries—Type 2 patients JW and JR. Based on Medtronic's Model, Dr. Krishnamurthy was able to bill CPT codes 95250, 95251 and 99214 for these patients, though Medtronic expended the effort associated with these codes.

271. As part of the iPro clinic model, Dr. Krishnamurthy allowed Medtronic to identify patients who Medtronic viewed as pump candidates, interact with those patients outside the presence of the physician, convince the patients to agree to the pump, fill out the pump order form, and process the insurance and shipping of the pump. Dr. Krishnamurthy's practice was Medtronic's fastest growing pump-shipping office in Relator's territory. By way of example, as a result of the iPro clinic held on October 25, 2010, Medicare beneficiary JW was subsequently prescribed a pump and U-500 insulin on January 24, 2011.[11]

272. In January, 2011, Dr. Krishnamurthy enrolled in the Connect the Dots program. As part of her enrollment, she filled out a survey that indicated she had 200 insulin-taking patients. Of those insulin-taking patients, 85% were Type 2 (15% of which were on pump therapy), and 15% were Type 1 (50% of which were on pump therapy). She disclosed owning two iPro units, but performed 4-6 iPro procedures weekly. This was only possible because she used Medtronic-provided iPro units

[11] While Medtronic's underlying records to which Relator had access (such as underlying claims records and shipping lists) did not regularly track pump models and serial numbers, Relator provides them in this filing when identified in the underlying records. For example, J.W.'s pump model is MMT-723NAS and serial number is PAR887630H.

(loaned to her for free) in addition to her own. She also represented that she expected the number of patients on iPro procedures would increase by 25% over the following three months, and that the number of patients that received a pump would increase by the same percentage. She also disclosed that over the previous three months, she had started 7-10 new patients on pump therapy.

273. Relator is personally aware that Dr. Krishnamurthy approved pumps for many government-insured patients as a *quid pro quo* for the financial benefit she obtained from the Medtronic-run iPro clinics, as well as for substantially free Nurse in Office help from Chris Makinson, frequent lunches and dinners, and her involvement in the Connect the Dots program. By way of further example, Relator retained notes on Medicare beneficiary CP's AOB that indicated CP received a pump (and by extension insulin) and an iPro Tracker reveals CP attended an iPro clinic on February 3, 2011.

274. Representative claims to government healthcare programs referred by Dr. Krishnamurthy while in a prohibited financial relationship with Medtronic in violation of the AKS and Stark Laws are reflected in Appendix A. (Of note, in the Appendix and otherwise in this public filing, all patient names are redacted to protect the patient's privacy. Names can be later provided pursuant to a qualified protective order under HIPAA).

b. **Dr. Mary Carroll.**

275. Dr. Carroll joined the Bend Memorial Clinic practice in Bend, Oregon in 2005. Bend Memorial Clinic is a large primary care and specialty clinic. Prior to her arrival, Bend Memorial Clinic had not used insulin pumps at any significant volume level, and had not received visits from Medtronic. Dr. Carroll had a previous

relationship with Medtronic and requested Medtronic to train her staff at Bend, Jennifer McDonough and later Tonya Koopman, and requested a center contract. Dr. Carroll understood the compensation that was available through initiating and upgrading pumps and was eager to partner with Medtronic. During her first lunch with Relator and Chris Makinson, they explained to Dr. Carroll the economic value to her of integrating new patients to the pump. As a result, she began prescribing twenty to thirty pumps per year in her first few years. In addition, the other doctors at her practice, to include Dr. Rick Goldstein began prescribing Medtronic pumps so that Bend could benefit from training the patients. Relator estimates that Bend doctors prescribed pumps for over one hundred patients. Relator estimates that at least 35 percent of the pump recipients were Medicare beneficiaries.

276. By way of example, documents retained by Relator (ship lists) show Medicare beneficiary J.L. was shipped a pump on November 11, 2008, K.L. on June 2, 2009 and W.E. on June 29, 2009.

277. A Strategic Account Plan for Fiscal Year 2009 for Bend Memorial Clinic reveals the success of Medtronic's kickbacks. Its summary: "tapped out the Type I population." The practice had 130 diabetes patients, all of which took insulin. 120 of these patients were on the pump, 100% of these on Medtronic pumps. Dr. Carroll's "belief in IPT" scored a 10, as did her "loyalty to MDT". Relator's next focus was on Bend's Type II patients, of which Bend had 100, 75 of whom took insulin, and 25 of those were already on the pump. Up until that time, the Strategic Account Plan noted that the clinic as yet did not have any upgrade accounts, therefore Bend had received reimbursement of $42,500 for initial training alone. As accounts began receiving

upgrades in 2010 and 2011, Bend would have received an additional $325 for training each of those patients. Further, Medtronic provided Bend's CPT, Tonya Koopman with regular free lunches and a paid trip to Las Vegas for a Connect the Dots Symposium.

278. By way of example, documents retained by Relator (Medtronic training compensation forms) show Medicare beneficiary DF received a pump (Model: Paradigm 712/SN: 104034) on November 23, 2005 and on January 13, 2006 Medtronic approved payment of $425 to Bend for training. Similarly, Bend submitted a Compensation Request Form for Medicare beneficiary JV on March 29, 2006 for $425 and Relator recalls Medtronic approved payment.

279. In or about January 2011, Medtronic reduced its reimbursement for upgrade training from $325 to $100 (eliminating the $225 start-up training payment). As previously described, Dr. Carroll's CPT, Tanya Koopman, wrote and threatened to stop recommending Medtronic's insulin pumps to its patients if Medtronic stopped paying the $225 start-up training payment. To continue getting this business, Medtronic agreed to continue to pay the kickback rather than losing over 20 pumps per year from Dr. Carroll.

280. Representative claims to government healthcare programs referred by Dr. Carroll while in a prohibited financial relationship with Medtronic in violation of the AKS and Stark Laws are reflected in Appendix A.

c. Dr. Latha Radhakrishan.

281. From 2005-2009, Dr. Latha Radhakrishnan practiced in Salem, Oregon and owned shared office space at the Physician's Building Group in Salem, Oregon. Prior to her contact with Medtronic, she had little to no exposure to insulin pump therapy

or iPro clinics. Relator first met with her in 2005 and pitched CGMS (the earlier version of iPro) and the use of his nurse, Chris Makinson. Dr. Radhakrishnan took advantage of both arrangements. Medtronic supplied her with a Nurse in Office and all CGMS products and supplies. In return, Dr. Radhakrishnan referred to Medtronic pump patients. Relator regularly reviewed the Economic Model with Dr. Radhakrishnan.

282. On average, Medtronic provided Dr. Radhakrishnan with at least 1 day of Nurse in Office service per week. Occasionally, Medtronic provided Dr. Radhakrishnan with 2 days of service per week. In return, Dr. Radhakrishnan prescribed 30 pumps her first year and over 70 pumps before she left Salem in 2009. Based on Relator's knowledge of her practice, he estimates that at least 30 percent were government-insured beneficiaries.

283. A Strategic Account Plan for Fiscal Year 2009 for Dr. Radhakrishnan, combined with Drs. Garrison and Chamberlain (who were both described as part-time at Physician's Building Group) reveals the success of Medtronic's kickbacks. Dr. Radhakrishnan's "belief in IPT" scored a 10, as did her "loyalty to MDT". Medtronic's share of pumps was 100%. It noted, however, that "Dr. Radhakrishnan has slowed her pace after prescribing all new pumps over the past few years." The doctors had 300 Type 1 patients who were insulin-taking, 200 of which were on the pump as of 2009. The practice had 50 Type 2 patients who were insulin-taking, 40 of which were on the pump as of 2009. Like Dr. Radhakrishnan, Drs. Garrison and Chamberlain took advantage of Medtronic's Nurse in Office program and made frequent use of Chris Makinson's services and referred 100% of their pump patients to Medtronic.

284. By way of example, Medicare beneficiary (and Dr. Radhakrishnan's

patient) M.C. was shipped a pump on July 23, 2009 and Champ/VA beneficiary OW was shipped a pump on April 8, 2008.

285. The free benefits and incentives provided to Dr. Radhakrishnan constitute remuneration under both AKS and Stark, and form a prohibited financial relationship under Stark. Once this prohibited financial relationship is formed, Medtronic violates the express prohibitions of the Stark laws by submitting and causing the submission of claims for patients referred by Dr. Radhakrishnan. Because the purpose of the payment was to induce Dr. Radhakrishnan to order pumps for her patients, Medtronic also violates the AKS, compliance with which is a material condition of payment of government healthcare claims. The foreseeable results of Medtronic's remunerative relationships are claims to government healthcare programs, including claims by Medtronic for diabetic pumps for the patients of Dr. Radhakrishnan, claims by pharmacies for insulin for those patients, and claims by Dr. Radhakrishnan for evaluation and management services for each of those patients.

286. Representative claims to government healthcare programs referred by Dr. Radhakrishnan while in a prohibited financial relationship with Medtronic in violation of the AKS and Stark Laws are reflected in Appendix A.

d. **Dr. Rajesh Ravuri.**

287. Dr. Rajesh Ravuri is a primary care physician in Coos Bay, Oregon. He is part of the North Bend Medical Center, and owns his own practice. Relator first visited him in 2008. To Relator's knowledge, he had never before prescribed an insulin pump or conducted an iPro procedure. Relator believes the majority of Dr. Ravuri's patients were government-insured as Coos Bay is a very elderly and a poor population. Dr.

Ravuri was very interested in learning about the financial benefit to his practice from Medtronic's iPro clinics and training. Relator regularly discussed with him the Economic Model and demonstrated how he could make money using iPro, based on various volumes, and training. Relator delivered the Medtronic-line that reimbursement from pump training alone could pay for an additional employee to conduct the training and that everything else is just added profit to the office.

288. Beginning shortly after Relator's first lunch presentation of the Economic Model, Medtronic began conducting iPro clinics in the office and finding patients to convert to NPNT (new patients to pump therapy). Medtronic also trained Dr. Ravuri's medical assistant to become a CPT and executed a training contract. Dr. Ravuri also enrolled in Connect the Dots, being accepted February 12, 2010.

289. Dr. Ravuri eventually purchased his own iPro units and many months later began performing his own procedures without the use of Medtronic's demo devices and sensors as he had previously. At the time of Relator's termination, Dr. Ravuri had prescribed approximately 30 insulin pumps, at least half of which Relator estimates were Medicare or Medicaid patients.

290. By way of example, on February 25, 2011, Relator received an email from Michael Kim confirming that Medicare beneficiary JR (Dr. Ravuri's patient) was shipped a pump. Further, Medicare beneficiary DH was shipped a pump on October 18, 2010.

291. Medtronic was also extremely focused on incentivizing Dr. Ravurri because he was interested in acting as an insulin pump and CGM specialist in the area. There was not an endocrinologist within a 2 to 3 hour drive of the coast. Therefore, in the summer of 2010, Medtronic scheduled an expensive dinner program where Dr.

Ravuri hosted and promoted his Medtronic services to local doctors. Additionally, Medtronic sponsored and paid for lunches with other primary care physicians for the same purposes. This plan was successful, as other PCPs in the area referred patients to Dr. Ravuri to put on the pump. By way of example, a local PCP, Dr. Carla Antola, referred Medicaid beneficiary AK to Dr. Ravuri. Dr. Ravuri responded by submitting to Medicaid a request for a Medtronic Insulin Pump on December 8, 2010.

292. Representative claims to government healthcare programs referred by Dr. Ravuri while in a prohibited financial relationship with Medtronic in violation of the AKS and Stark Laws are reflected in Appendix A.

e. **Dr. Rodney Michaels.**

293. Dr. Rodney Michaels is an endocrinologist and the owner of Firehouse Diabetes Center in Salem, Oregon. When Relator joined Medtronic in 2004, Dr. Micheals introduced himself as "one of the largest prescribers of Medtronic insulin pumps in Oregon." Dr. Michaels already had a training contract for Firehouse, and his Certified Pump Trainer was Lindita Nako. Physician Assistant Barbara Britsch also practiced at Firehouse. In return, Dr. Michaels prescribed well over 100 pumps during Relator's tenure at Medtronic. Based on his knowledge of the practice, Relator estimates that 25 percent of these patients were government-insured beneficiaries.

294. By way of example, documents retained by Relator (ship lists) show that Medicare beneficiary W.D. was shipped a pump on 2/4/2009 and Medicare beneficiary L.P. on 1/2/2008, the latter of which was under PA Britsch's care.

295. A Strategic Account Plan for Fiscal Year 2009 for Dr. Michaels reveals the success of Medtronic's kickbacks. Its summary: "Dr. Michaels says he has put over 500

patients on the pump since has been in business." The competitive assessment noted that Medtronic's share of this practice was 96%. He had 350 insulin-taking Type 1 patients, 300 of which were on the pump and 500 insulin-taking Type 2 patients, 200 of which were on the pump.

296. Firehouse was so interested in reaping the training payment that it kept track of when pump patients were out of warranty for Medtronic. By way of example, in 2011, Lindita Nako gave Relator a list with several patient names and phone numbers to call and convert to upgrades so that its CPT could receive training payments.

297. Representative claims to government healthcare programs referred by Dr. Michaels while in a prohibited financial relationship with Medtronic in violation of the AKS and Stark Laws are reflected in Appendix A.

f. **Dr. John Gallen.**

298. From 2004 to approximately 2006, Dr. John Gallen worked in Medford, Oregon at Medford Diabetes, Endocrinology and Metabolism, alongside Dr. Patrick McCarthy, the clinic owner. Medford Diabetes took advantage of Medtronic's lucrative training payments, utilizing CPT Terri Martisak and Dr. McCarthy referred pump patients to Medtronic regularly. In approximately 2006, Dr. McCarthy closed the practice and moved to Bend, Oregon where he continued to take advantage of Medtronic's training payments, utilizing Rita Shearer. Examples of patients referred by Medford Diabetes owner, Dr. McCarthy, are provided at Appendix A.

299. After Dr. McCarthy moved his practice, Dr. Gallen began practicing at the Medford Medical Clinic. At Medford Medical, Relator presented the Economic Model to Dr. Gallen at scheduled lunches and discussed the opportunity of a training contract.

Dr. Gallen was very interested in the financial incentives laid out in the training contract and executed a contract for Medford Medical, using his CPT Marianne Neito, and shortly thereafter became one of the territory's largest pump prescribers.

300. In 2010, after aggressively marketing iPro, Medtronic nurse Chris Makinson began conducting iPro procedures. Medtronic provided all of the equipment and disposables for the procedures. Medtronic also made Dr. Gallen a paid speaker and sponsored a speaker program to the local educators. Medtronic also brought Dr. Gallen to its headquarters as part of a customer visit program.

301. From 2006 until Relator's termination in February 2011, Dr. Gallen prescribed approximately 100 pumps. Based on his knowledge of the practice, Relator estimates that approximately 30 percent of these patients were government-insured beneficiaries.

302. By way of example, documents retained by Relator (ship lists) show that Medicare beneficiary F.K. was shipped a pump on 8/11/2009 and Tricare beneficiary K.B. on 4/6/2009.

303. Representative claims to government healthcare programs referred by Dr. Gallen while in a prohibited financial relationship with Medtronic in violation of the AKS and Stark Laws are reflected in Appendix A.

g. **Dr. Alan Kelly.**

304. Since 2006, Dr. Alan Kelly has practiced at the Institute of Diabetes and Endocrinology in Medford, Oregon, which he co-owns with Dr. Richard Eddy. In approximately 2007, Certified Pump Trainer and Medtronic contractor Sue Amidon began working for the practice. Relator was able to present Medtronic's Economic

Model to the practice and execute a center contract. Whereas prior to 2007, the practice had only prescribed a few pumps each year, with a center training contract, the practice became a high volume pump prescriber.

305. In addition to the financial incentives from training, Dr. Kelly became a paid speaker for Medtronic, visited Medtronic's headquarters as part of a customer visit program, participated in Connect the Dots and was provided free sensors for his iPro unit. Up until the time of Relator's termination, Relator estimates that Dr. Kelly and the Institute of Diabetes and Endocrinology (including Dr. Eddy and Dr. Hungerford who joined the practice in 2010) prescribed over 90 pumps, approximately 30 percent of which were to government-insured beneficiaries.

306. By way of example, documents retained by Relator (ship lists) show that Medicare beneficiary (a patient of Dr. Eddy) M.R. was shipped a pump on 11/5/2009 and that Medicare beneficiary (a patient of Dr. Kelly) D.C. was shipped a pump on 11/18/2008.

307. Representative claims to government healthcare programs referred by Dr. Kelly while in a prohibited financial relationship with Medtronic in violation of the AKS and Stark Laws are reflected in Appendix A.

h. Other Representative Claims Examples.

308. The free benefits and incentives provided to the above-identified doctors constitute remuneration under both AKS and Stark, and form a prohibited financial relationship under Stark. Once this prohibited financial relationship is formed, Medtronic violates the express prohibitions of the Stark laws by submitting and causing the submission of claims for patients referred by the providers. Because the purpose of the

payment was to induce the above-identified doctors to order pumps for their patients, Medtronic also violates the AKS, compliance with which is a material condition of payment of government healthcare claims. The foreseeable results of Medtronic's remunerative relationships are claims to government healthcare programs, including claims by Medtronic for diabetic pumps for the patients of these providers, claims by pharmacies for insulin for those patients, and claims by these providers for evaluation and management services for each of those patients.

309. Other examples of claims resulting from free benefits and incentives offered to the providers, in addition to the ones identified above, are attached at Appendix A. For each claim example, the identity of the provider who was incentivized to submit the claim is provided, and the specific remuneration intended to induce the provider is also explained. The Appendix identifies approximately 29 providers with 95 representative claims examples. Additional providers who were incentivized by Medtronic are included below, categorized by remuneration provided:

I-Pro Clinics

Dr. Erik Kline, West Olympia Internal Medicine (Olympia, WA)
Dr. Christina Orr, Vancouver Clinic (Vancouver, WA)
Dr. Michael Decker, Vancouver Clinic (Vancouver, WA)
Dr. Elizabeth Stephens, Providence Health Services (Portland, OR)
Legacy Emmanuel Medical Center (Portland, OR)
Dr. Nancy Kurosh (Portland, OR)
Dr. Richard Kirkpatrick (Longview, WA)
Dr. Anthony Fritz Chehalis, Centralia Specialty Center (Centralia, WA)
Beth Schwenk, CDE, Providence Seaside, Seaside Dieticians and Nutritionists (Seaside, OR)
Dr. Shelley Hartman (Hillsboro, OR)

Individual Providers Offered and Paid Training Contracts:

Sara Hohn (OHSU, Portland, OR)

Susan Amidon (Medford, Oregon)
Jacque Corey (Eugene, Oregon)
Rita Shearer (Redmond, Oregon)
Sue Humiston (Sisters, Oregon)
Teresa Martisak (Medford, Oregon)
Joy Cook (Medford, Oregon)
Debbie Pauls (Corvallis, Oregon)

Provider Groups Offered and Paid "Center Contracts":

Cascade Health Solutions (Eugene, OR)
Asante Diabetes Center (Medford, OR)
Black Oak Clinic (Medford, OR)
Good Samaritan Hospital (Corvallis, OR)
Sky Lakes Medical Center (Klamath Falls, OR)
The Samaritan Lebanon Community Hospital (Lebanon, OR)
Providence Medical Group (Providence, OR)_
Portland Diabetes Center (Portland, OR)

II. FALSE CLAIMS RESULTING FROM OFF LABEL USES THAT ARE NOT SAFE OR EFFECTIVE.

310. Medtronic promotes its insulin pumps for two distinct off-label uses. First, though the insulin pump has FDA approval for use only with Humulin insulin U-100 (meaning that it has a concentration of 100 units per ml), Medtronic uses false and misleading information to induce providers to prescribe it with a 500% higher-concentration insulin for Type 2 patients. This product is called U-500, and it is FDA-approved only for administration by injection. The reason that Medtronic urges physicians to prescribe off-label is that the insulin requirements of Type 2 patients are higher than those of Type 1 patients, and the pump's reservoir is of insufficient size to accommodate enough U-100 insulin to supply the patient's requirements. However, the use of the pump with U-500 insulin is unsupported by evidence of safety and effectiveness, and is not FDA-approved or supported in the literature or on any compendium. It also creates significant safety issues. Second, although its adult

insulin pumps have no approved indication for pediatric patients, Medtronic uses false and misleading information to induce providers to order the adult patient for children despite knowing that the FDA has specifically determined that the pediatric use of the adult pump raises safety issues and disallowed such use.

311. "Any promotion of a [drug or] device for any indication not approved or cleared by the FDA and indicated on the label is considered an 'off-label' promotion and is unlawful." *United States ex rel. Nowak v. Medtronic, Inc.,* 806 F. Supp. 2d 310, 317 (D. Mass. 2011) *citing* 21 U.S.C. § 331(d). The Court further found that in order to sustain a claim that the illegal off-label promotion of drugs and medical devices also resulted in false claims to government healthcare programs, the illegal off-label promotion must be capable of influencing the government's decision as to whether to pay the claim. . *Nowak*, 806 F. Supp. 2d at 350-51.

A. Compliance with Material Conditions of Payment Governing Off-Label Use of Drugs and Devices.

312. Medtronic's practices involve the off-label use of drugs (U-500 insulin) as well as devices (insulin pumps) because the order of an insulin pump results in (1) a claim for the pump itself and (2) additional, distinct claims for the insulin used in the pump.

313. "While Medicare and Medicaid typically do not reimburse off-label prescriptions for drugs,…eligibility for reimbursement [of Category B medical devices] depends on whether the procedure performed is 'medically necessary' or 'reasonable and necessary.'" *Nowak*, 806 F. Supp. 2d at 347 (citations omitted).

1. Off-label Use of Insulin Pumps Are Not Covered and Payable Unless Based on a Determination of Safety and Effectiveness.

314. As a material condition of payment, Medicare requires that all items and services be "reasonable and necessary for the diagnosis or treatment of illness or injury." 42 U.S.C. § 1395y(a)(1)(A); *see also* 42 C.F.R. § 411.15(k)(l).

315. An item or service is "reasonable and necessary" for purposes of Medicare coverage if the contractor determines it is:

- *Safe and effective* and
- *Appropriate*, including the duration and frequency that is considered appropriate for the item or service, in terms of whether it is:
  - Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;
  - Furnished in a setting appropriate to the patient's medical needs and condition;
  - Ordered and furnished by qualified personnel;
  - One that meets, but does not exceed, the patient's medical need; and
  - At least as beneficial as an existing and available medically appropriate alternative.

Medicare Program Integrity Manual, § 13.5.1 (January 15, 2013) (emphasis added).

316. Medtronic's insulin pumps are Class II medical devices which have been approved for marketing by the FDA under the "510(k) process," which allows the manufacturer to market and sell a device which is a "substantial equivalent" to a device which has already obtained premarketing approval for the same use, and where it certifies that the information submitted pursuant to the 510(k) process is "truthful and

accurate." 21 U.S.C. § 360; 21 C.F.R. § 807.87(k).

317. Premarketing approval is required so that the manufacturer furnishes detailed information about the device's testing, design, components, performance standards, manufacturing, packaging, and labeling" sufficient to reasonably assure the FDA that the device is safe and effective. 21 U.S.C. § 360e(c)(1); 21 C.F.R. § 814.20 (1994)); 21 U.S.C. § 360c (a)(1)(C). The determination that a medical device is safe and effective is necessarily predicated on factors which include the condition of the device's intended beneficiaries and the circumstances of the device's intended use. 21 C.F.R. § 860.7(b).

318. If the manufacturer wishes to market a new, unapproved use for its product, it must first obtain FDA approval so that its labeling is changed to indicate the limits of any FDA approval of such additional or substitute uses. 21 C.F.R. § 807.81(a)(3).

319. Off-label use of insulin pumps is only covered and payable if there is a determination that the use is safe and effective

2. <u>Off-Label Use of the Insulin Is Not Covered and Payable.</u>

320. Medtronic's pump is approved for use only with u-100 insulin. The off-label use of drugs, including the off-label use of U-500 insulin, is not covered and payable by government healthcare programs.

321. A prescription drug is not a "drug or biological" for Medicare reimbursement purposes unless it is included, or approved for inclusion, in "the latest official edition of the United States Pharmacopoeia National Formulary (USP-NF), the United States Pharmacopoeia-Drug Information (USD-DI), or the American Dental

Association (AOA) Guide to Dental Therapeutics, which contain medically accepted uses for generic and brand name drug products." MBPM, Ch. 50.1

322. A drug is safe and effective for reimbursement-eligibility purposes only when approved for marketing by the [FDA] and used for indications specified on the labeling. MBPM at Ch. 50.4. Unlabeled uses of a drug are presumptively not safe and effective, and can be covered only when "the carrier determines the use to be medically accepted, taking into consideration the major drug compendia, authoritative medical literature and/or accepted standards of medical practice." *Id.* at 50.4.2. Also, a drug cannot be reasonable and necessary if the "injection method [is] not indicated." *Id.* at 50.4.3(2) ("Examples of Not Reasonable and Necessary").

323. State Medicaid programs cover only outpatient drugs dispensed by prescription and approved as safe and effective under the FDCA, 21 U.S.C. §§ 355, 357, and do not allow coverage for "a drug or biological used for a medical indication which is not a medically accepted indication." 42 U.S.C. § 1396r-8(k)(2),(3). A "medically accepted indication" includes "any use for a covered outpatient drug which is approved under the [FDCA], or the use of which is supported by one or more citations included or approved for inclusion in … the compendia [recognized by the Medicaid statute" - the American Hospital Formulary Service Drug Information, the United States Pharmacopeia-Drug Information (and its successor publications), and the Drugdex Information System. *Id.* at § 1396r-8(g)(1)(B)(i).

324. Finally, other government healthcare programs follow suit, and restrict coverage to labeled uses unless comparable criteria are met.[12]

[12]TriCare, for example, restricted coverage of drugs and devices to only on-label uses from 2007 through 2012, when it amended its manual to permit off-label uses only when, consistent

3. Medtronic Promotes its Insulin Pump Off-Label for Use with High Potency U-500 Insulin.

325. In the United States insulin is sold in two strengths: U-100 and U-500. U-100 insulin contains 100 units of insulin activity per mL of fluid. U-500 is five times more concentrated and contains 500 units of insulin activity per mL of fluid.

326. Medtronic has a joint venture with Eli Lilly & Co. ("Lilly") to market Lilly's insulin. Lilly sells both U-100 insulin and U-500 insulin. Lilly is the only manufacturer of U-500 insulin. Its U-500 insulin is called Humulin R U-500.

327. Because of the high potency of U-500 insulin, extreme caution must be taken to avoid overdosing on it. The FDA has only approved U-500 insulin for subcutaneous injection, and not for use in insulin pumps. The FDA-approved Prescribing Information ("P.I.") for Humulin U-500 insulin, the only brand of U-500 insulin approved by the FDA, states: "Humulin R U-500 is for subcutaneous injection only."

328. Because the risks of dosing confusion with U-500 insulin are substantial and the consequences grave even when administered by syringe (as the label requires), in March 2011 the FDA ordered that additional safety warnings be added to the P.I. for Humulin U-500. The new warnings state:

PRECAUTIONS

Dosing Confusion/Dosing Errors

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with the Medicare definition, the use is medically necessary ***and*** the carrier has approved it based on "demonstrations from medical literature, national organizations, or technology assessment bodies show[ing] that the off-label use of the device is safe, effective and in accordance with nationally accepted standards of practice in the medical community." TriCare Policy Manual (2008 Ed.), Ch.8 § 5.1. at 2.3 (2012); Tricare Policy Manual (2008 Ed.), Ch. 8 § 9.1 at 2.2.5; *see also* 32 C.F.R. Part 199; CHAMPVA Policy Manual, Chapter 2, § 22.1 (2011).

> Medication errors associated with Humulin R U-500 have occurred and resulted in patients experiencing hyperglycemia, hypoglycemia or death. The majority of errors occurred due to errors in dispensing, prescribing or administration.[13]

329. Medtronic's insulin pump is approved by the FDA for use with U-100 insulin only, and not for use with U-500 insulin. On each occasion that Medtronic has applied to the FDA for approval for one of its insulin pumps, Medtronic has represented that the pump is only intended for use with U-100 insulin, and the FDA has approved the product on that basis. A representative example is the May 21, 2004 FDA approval of the Medtronic Paradigm Model 515/715 Insulin Pumps. The FDA approved the pumps based upon Medtronic's representation that the pumps "are designed to deliver 0.00 to 35.00 units of U100 insulin per hour in basal rates and up to 25.00 units of U100 insulin per meal or meal bolus." Emphasis added.

330. Notwithstanding these legal restrictions and dangers posed to patients, Medtronic vigorously promotes its insulin pump paired with U-500 insulin for obese and insulin-resistant Type 2 diabetics. Medtronic's conduct causes off-label prescriptions to be written for both the insulin pump and the U-500 insulin.

331. Medtronic's motivation for engaging in this unlawful conduct is the desire to sell more insulin pumps to patients with Type 2 diabetes. Historically, Medtronic has sold very few pumps to insulin-dependent patients with Type 2 diabetes. These patients are typically overweight or obese, and therefore require large amounts of insulin--often several hundred units a day. Medtronic's largest insulin pump only holds a maximum of 300 units of U-100 insulin, which renders the pump impractical for these patients since they would have to change the reservoir constantly, instead of every three days (as is

[13] Described on the FDA website at http://www.fda.gov/Safety/MedWatch/SafetyInformation/ucm250517.htm.

true for patients with Type 1 diabetes).

332. Instead of recognizing that it is constrained to market its pump for the purpose for which it has been determined safe and effective, Medtronic holds U-500 insulin out as the solution to the inappropriateness of the pump for Type 2 patients. When U-500 is placed in a pump with a 300 unit reservoir, the pump holds the equivalent of 1500 units of U-100 insulin, rather than the 300 units for which it is designed and approved.

333. Beginning in or about 2007, Medtronic began promoting its insulin pump with U-500 insulin to insulin-dependent Type 2 diabetics. This promotion squarely disregards the conditions of the FDA's approval of both of these products.

334. Medtronic knew that physicians who treat Type 2 patients, and the Type 2 patients themselves, would be susceptible to this off-label promotional practice for two reasons. First, as previously discussed, going on pump therapy generally saves Medicare patients money because it shifts the cost from his or her prescription drug plan under Medicare Part D (covering MDI therapy at a higher out of pocket cost) to Medicare Part B (covering pump therapy with a co-pay).

335. Second, obese Type 2 diabetics are considered generally to have a poor record of adhering to complicated insulin injection regimens. For these patients, going on pump therapy is superficially attractive because it relieves them of having to self-administer multiple daily injections of insulin.

336. However, there is a compelling reason why U-500 insulin is not approved for use in Medtronic's insulin pumps for *any* patient population: It creates serious health risks for patients.

4. Lack of Safety and Efficacy.

337. A significant health risk with use of U-500 is dosing confusion. All of the measurements on Medtronic's insulin pump are in units of U-100 insulin. The pump does not have the ability to convert to units of U-500 insulin. If U-500 insulin is substituted for U-100, the patient herself must remember to divide by five the insulin units displayed on the pump. For example, if the patient needs 20 units of U-100 insulin, he/she must divide the pump's recommended dose by five and just take four units of U-500 insulin. If the patient does not remember and takes 20 units, the patient will have actually dosed 100 units.

338. Since most recommended dosages are in tenths of a unit, the math becomes even more complex. For example, if the recommended dose from the pump is 23.25 units of insulin, the correct does of U-500 insulin is 4.65 units. Even if they remember to divide by five, patients can easily make a calculation error. A mistake in calculation creates significant risk of overdosing.

339. The risk of overdosing with insulin is that it will bring the patient's glucose levels down too low, resulting in hypoglycemia. For example, if an individual using U-500 insulin in the pump intends to deliver a bolus dosage of 150 units of insulin and forgets to set the dosage meter on one-fifth of that amount, the pump will deliver the equivalent of 750 units of insulin. Such an overdose can cause extreme hypoglycemia, which can lead to loss of consciousness, diabetic coma, and death.

340. These risks are so significant that, in 2008, the FDA included U-500 insulin in its first quarterly report of drugs with "potential safety issues." The FDA listed

the safety issue as "dosing confusion."[14] The FDA reiterated the risk of dosing confusion in another report, entitled "Mixups between Insulin U-100 and U-500," in the September 2008 edition of "FDA Patient Safety News."[15] As a result of the risks attendant just to injections, the FDA issued a safety warning to be added to the U-500 injectable Prescribing Information.

341. A second health risk attendant to substitution of U-500 for U-100 insulin in the pump stems from the fact that U-500 insulin has a different time action profile than certain brands of U-100 insulin. The time action profile of insulin is defined by its "onset, peak and duration." "Onset" refers to how long the drug takes to start working; "peak" refers to how long it takes to reach its peak concentration; and "duration" is how long the insulin effect lasts.

342. The U-100 insulin that is used in insulin pumps is called "rapid acting" insulin. The leading brands are Lilly's Humalog, Novo Nordisk's Novalog, and Sanofi-Aventis's Apidra. Rapid-acting insulin works quickly: Its onset is almost immediate. It peaks quickly (30-90 minutes), and is out of the body quickly (within four hours). In contrast, the only brand of U-500 insulin sold in the United States, Humulin R U500 (jointly marketed by Lilly and Medtronic), is "regular acting," not "rapid acting." Regular-acting U-500 insulin has a slower time action profile than rapid-acting U-100 insulin. This creates the risk for pump users who switch from U-100 to U-500 insulin to have prolonged hypoglycemic reactions due to the drug staying in the system much longer

[14] This report can be viewed on the FDA's website at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm085914.htm.

[15] This report can be viewed at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/psn/transcript.cfm?show=79.

than U-100 insulin. Also, bolus dosing methodology in a pump is calibrated for rapid-acting insulin, but U-500 has a delayed activity, making it more difficult to determine the correct bolus dosing. These facts add complexity for the patient and greater risk of misdosing when U-500 insulin is substituted for U-100 in the pump.

343. The risks associated with the combination of the off-label use of the pump with off-label U-500 Insulin has led to Adverse Event Reports, which illustrate the risks of using U-500 in an insulin pump. Medtronic does not disclose the existence of Adverse Events to providers or patients.

344. On February 13, 2005, for example, a patient using U-500 insulin in a Medtronic insulin pump experienced an FDA-reported Adverse Event. According to the Adverse Event report, the patient was hospitalized for low blood glucose levels. Medtronic determined that "[t]he programming, insulin concentration and bolus history were not accurate."

345. On March 5, 2011, a patient using U-500 insulin in a Medtronic insulin pump experienced an Adverse Event which was reported to the FDA. According to the Adverse Event report, "It was reported that the customer was treated in the emergency room due to hyperglycemia, with blood glucose readings over 500 mg/dl. . . . The customer . . . stated that he recently had changed to u500 insulin from the u100 insulin and that has changed his averages. . . . The customer further stated that he had only given himself manual boluses instead of using the bolus wizard. Nothing further was reported."

346. Patients using U-500 insulin in other manufacturer's insulin pumps have also experienced Adverse Events, because the same risks are present when using U-

500 off-label.

347. For example, in approximately December 2009, a patient using U-500 insulin in an insulin pump manufactured by Animas Corp experienced an Adverse Event which was reported to the FDA. According to the Adverse Event report, on the date of the incident the patient:

> woke up in an ambulance after passing out on the floor. The pt's blood glucose was around or below 30 mg/dl and was treated at the hospital. He indicated that the incident was related to the insulin he was using at the time. The pt was using u500 insulin when the pump was designed for u100 insulin. He indicated that after he switched to u100 humalog, his bg [blood glucose] was fine. There is no indication that the pump malfunctioned; however, this complaint is being reported because the pt reportedly became hypoglycemic and required medical intervention when he used u500 insulin with the pump.

Notably, the manufacturer's response included that the pump was designed for U-100 insulin.

348. On January 30, 2006, a patient using U-500 insulin in an insulin pump manufactured by Smith Medical (formerly Deltec, Inc.) experienced an Adverse Event which was reported to the FDA. According to the Adverse Event report, the:

> patient had become unresponsive on 01/30/06 due to hypoglycemia and the paramedics had to be summoned. The patient's md reported that the patient uses u-500 humulin regular insulin in his insulin pump. . . . The md believed this [adverse event] to be the result of an incorrect calculation of insulin based on his correction formula. The doctor was informed [by the manufacturer] that the device was only labeled to be used with u100 insulin."

Notably, the manufacturer's response included that the device was only labeled to be used with U-100 insulin.

349. On October 27, 2010, a patient using U-500 insulin in an insulin pump manufactured by Animas Corp experienced an FDA-reported Adverse Event. According to the Adverse Event report, the patient was hospitalized due to inadvertent

infusion of insulin. The manufacturer responded to the report of the event by stating, *inter alia*, that "[t]he pump is not indicated for use with u500 insulin."

350. Simply put, use of U-500 in an insulin pump has not been demonstrated to be safe and effective for medical use, and *is not* safe and effective. Remarkably, Medtronic's Product Manuals for each of its Insulin Pumps state that the pump is intended only for use with U-100 insulin. A representative example is the Product Manual for the MMT-523/723 insulin pump, which states at page 47:

> The Paradigm pump is intended for use with U100 insulin. The following insulins have been tested by Medtronic MiniMed and found to be safe for use in Paradigm REAL-Time insulin pumps (MMT-523, MMT-723, MMT-523K, and MMT-723K):
>
> • Humalog
> • Novolog

Medtronic Paradigm REAL-Time Revel MiniMed User Guide, at 47 (emphasis added).

351. There has been no FDA finding that this use is safe and effective, and there is no substantiating clinical data to support safety and effectiveness. Medtronic's pump has not been subjected to the kind of rigorous testing required by the FDA to ensure that a new intended use can be safely employed in vulnerable patient population such as elderly diabetics.

352. The Centers for Medicare and Medicaid Services (CMS) has squarely determined that insulin-pump use is rarely indicated in the Medicare Type 2 diabetic population. After a review of the available clinical evidence, CMS determined that outcome data for pump therapy in Type 2 diabetes was almost non-existent; that there have been almost no large-scale randomized, controlled trials examining the use of pump therapy in Type 2 patients, and that the data that existed on pump therapy was

overwhelmingly not generalized to the Medicare population (discussing that the validity of data regarding a "young highly motivated population" is not extrapolatable to the Medicare population). CMS Decision Memo at 13, 20. "This lack of information on the elderly coupled with potential increased risks and problems with the devices demonstrated by frequent FDA bulletins all support a restrictive policy for [Type 2] Medicare beneficiaries." CMS Decision Memo at 20. These findings are amplified when combining the risk associated with pump therapy for that population with the risks associated with use of U-500.

353. There is no evidence of any carrier determination in any instance that the off-label use of U-500 insulin is safe and effective. There is no National or Local Coverage Determination permitting off-label use. There is no support in the recognized compendia, nor the national medical literature, nor in clinical data, to justify a determination that the unlabeled use of U-500 and the pump is safe and effective and appropriate for treatment of government healthcare patients.

354. To the contrary, there is ample evidence of health risk that was not disclosed to providers or patients.

5. Medtronic's False Statements and Misrepresentations Regarding Use of U-500.

355. Despite these health risks and without presenting the FDA with any evidence that its pumps are safe and effective with U-500 insulin, Medtronic is actively promoting the use of U-500 insulin in its pumps to obese and insulin resistant Type 2 diabetics through the use of false statements, material omissions and misleading information.

a. Medtronic Does Not Disclose the Health Risks or that the Use is Off- Label.

356. When promoting the use of U-500 with the pump, Medtronic does not disclose the health risks to providers, nor does Medtronic identify that the use if off-label is off-label.

357. Rather, Medtronic initiates the conversation about U-500. For example, Medtronic provides its Territory Managers with copies of the Prescribing Information ("P.I.") for U-500 insulin and instructs them to distribute it to the physicians in their territories unsolicited. Relator received his copy of the P.I. from his District Manager, who received it from the Regional Sales Director Mike DiGiulio. As instructed, Relator emailed the P.I. to all of the diabetes health care professionals and diabetes educators in his territory. Relator's forwarding email to targeted providers for the pump (Medtronic does not sell insulin) stated, "Many people have requested information on U500. Here is some information from its manufacturer." Dr. John Gallen sent a reply email asking for information on the use of U-500 in Medtronic's insulin pump. Relator's DCM, Chris Makinson, visited Dr. Gallen's office to discuss this subject, and as a result Dr. Gallen put patients on the Medtronic pump using U-500 insulin.

358. Medtronic distributes to doctors and patients a conversion chart entitled "Conversion Chart for Use of u500 Insulin in Pump Set for u100 Insulin Concentration." The distribution of this chart facilitates and encourages the use of U-500 insulin in the insulin pump, but does not disclose that the pump is not intended for that use or warn of the dosing confusion risks.

b. Medtronic Uses Sham Studies Mislead the Providers.

359. Medtronic sales representatives and other employees were trained to, and

routinely did, lie to practitioners by telling them that U-500 was safe and effective for use with the pump. They bolstered these lies by presenting limited patient outcomes or private, practice-run "studies" without revealing that the patients were coached by Medtronic nurses or that the studies did not constitute meaningful clinical data.

360. For example, in 2009, two Medtronic employees in the Pacific Northwest District – Territory Manager Cathy Anderson and DCM Jennifer Minahan, RN – persuaded a Seattle endocrinologist, Dr. Shaista Quddusi, to conduct an informal study in which the doctor put 12 of her Type 2 diabetes patients on pump therapy. Seven of the patients used U-500 insulin in the pumps since they needed high dosages of insulin. Prior to the "study," the doctor did not put Type 2 patients on the pump. Due to the coaching the patients received from the DCM, all of the patients showed improvement. By sponsoring and participating in such informal "studies," Medtronic ensured that the patients studied produced what appeared to be good results on the pump; but the patients had close instruction and monitoring not available to Type 2 patients who did not have the constant personal attention of a Medtronic employee. As plainly shown by Medtronic's coverage criteria, the compliance behaviors of the patient are key to the success of pump therapy. Thus, the coaching of these informal "studies" produces misleading results regarding the appropriateness of Type 2 patients for the pump.

361. The two Medtronic employees were highly commended by senior management for this initiative, and the company disseminated the findings of their "study" throughout the region and the nation. Ms. Anderson and Nurse Minaham made presentations of their findings at District Sales Meetings and at a National Sales Meeting. By disseminating these findings and commending their initiative, Medtronic's

clear message to the sales force was to follow their lead and put more Type 2 patients on pump therapy with U-500 insulin. Medtronic rewarded Minaham for her role in this initiative by promoting her to a leadership position in charge of all of the DCMs in the Pacific Northwest District. She was promoted by Mike DiGiulio, Regional Sales Director.

362. The findings were used as a sales aid to market off-label U-500 use in the pump to doctors in Relator's territory and others throughout the region. When disseminating the findings of the informal study conducted by Ms. Anderson and RN Minaham, Medtronic did not tell providers the use was off-label; did not tell providers about the health risks associated with U-500 insulin dosage; and did not tell providers about the specific challenges encountered during the study relating to determining proper dosing of U-500 insulin in the pump. In an email to her District Manager on August 27, 2009, Territory Manager Cathy Anderson acknowledged that:

> U500 was a bit of a challenge. It is regular insulin so it peaks 3-5 hours later. Basals were increased at higher rates during the day to help with food and drop basals overnight because dinner insulin peaks in the middle of the night and put them at risk for nocturnal hypos. Basal was more 60% and bolus 40% and thank god for Carelink [the pump software]! The u500 pts called into the clinic weekly for the first month. Other than that you treat it like 5x stronger insulin.

363. In another email on the same day, Ms. Anderson conceded that dosing with U-500 was partially guess work: "All u500 users in the pump take more [insulin] if you calculate out units, <u>which I don't know if that is accurate or appropriate</u>? Anyway the results so far are great!" (emphasis supplied.) Despite the uncertainties with dosing, the company kept the U-500 patients on the pump.

364. Although Ms. Anderson acknowledged dangerous risks such as "nocturnal hypos" (episodes of hypoglycemia which occur while the patient sleeps,

which can be unusually dangerous) and that patients had to call into the clinic weekly due to confusion over the use of the pump with U-500, she did not report these difficulties back to the doctor. Instead, she wrote Dr. Quddusi, who prior to the study had not prescribed the pump for Type 2 diabetes patients, and provided the favorable statistical outcomes with a conclusion that "the results so far are great!" Thus, Medtronic personnel manipulated even this minimal, uncontrolled, company-sponsored "study" by withholding critical patient-safety information from the physician.

365. Ms. Anderson's study together with other "success stories" about U-500, became a standard part of Medtronic's campaign to expand off-label pump and U-500 sales. For example, when Ms. Anderson and Nurse Minahan were preparing a presentation for the District Sales Meeting, Ms. Anderson sent around an email on December 9, 2009, stating, " Travis [District Manager] asked Jenn and I to talk at the meeting. He wants us to talk on indications. . . . We were thinking type 2 review and U500 and some case studies . . . ." (December 9, 2009 Email from Cathy Anderson with Subject: District meeting topic).

366. Medtronic encouraged its employees to talk to groups outside the company about successes with U-500 insulin in the pumps. For example, in January 2009, Ms. Anderson was invited to give a talk to a medical practice in Seattle, Washington. She accepted the invitation and listed one of her intended topics as "type 2 and success with u500." (January 22, 2009 Email with Subject: CGMS/Pump talk to MDs).

367. Company managers routinely circulated to the sales force success stories about putting Type 2 patients on insulin pumps with U-500 insulin. For example, on

September 26, 2007, Doug Villiers, then District Manager for the Pacific Northwest District, circulated an email from Territory Manager Ed Stewart recounting his success at persuading a doctor to place a Type 2 diabetic patient on an insulin pump with U-500 insulin. In the underlying email, Ed Stewart explained:

> In an effort to expand indications with Dr. Chen, I asked him his opinions about pump therapy in Type 2 Diabetes with patients who are highly insulin resistant. He gave me lots of feedback which was great, and I shared with him some key takeaways from the Nielsen study [cited below], which looks at these specific patients, we discussed the results and I left a copy.
>
> Attached is a copy of an AOB [Authorization of Benefits insurance form signed by a purchaser of a pump] we received from him the NEXT DAY! It is for a 319 lb T2 [Type 2 diabetic], on 8-9 shots of U-500 . . . . (Very much like the patients in the study we reviewed!)

368. When District Manager Villiers circulated this success story, he commended it as an example of increasing sales by working "to expand indications." This was an apt description – it unilaterally expanded the pump's indications beyond those approved as safe and effective by the FDA and presented a four-patient outcomes case study as clinical evidence of safety and effectiveness. The prohibition against off-label promotion is designed precisely to prevent companies from usurping the FDA's role in this manner.

369. In an email on April 7, 2010, Mike DiGiulio, Regional Sales Director for the Western Region, forwarded to the Western region sales force a March 29, 2010 email from a DCM in Las Vegas, Nevada recounting her efforts to encourage Dr. Brian Berelowitz to prescribe insulin pump therapy for an insulin-resistant Type 2 patient requiring U-500 insulin:

> Dr. Brian Berelowitz is a highly regarded adult endocrinologist here in Las Vegas with a large practice. His office performs between ten and fifteen iPros per week on their patients and the doctor is an advocate for insulin pump therapy for nearly

> all Type 1 and insulin-requiring Type 2 patients in his practice. . . . I asked him if he could think of anyone who is very insulin resistant, someone he might be thinking of using U500 insulin on.

The Regional Director commended the DCM's initiative and called it a "great . . . success" when he forwarded the email to the Western Region sales force.

370. Medtronic trained its sales personnel to present home-made studies and anecdotal case examples as though they constituted clinical data of safety and effectiveness. In accounts where Medtronic wanted to "expand indications," the DCM (Diabetes Clinical Manager) would utilize an excel spreadsheet template called the patient or clinical "outcomes tracker" ("COT") on targeted patients who were new to pump therapy ("NPTs"). In effect, these were sham studies that convinced doubtful prescribers into becoming pump prescribers. The more successful "studies" were then circulated throughout Medtronic to be used in selling the effectiveness of the pump. They were misleading to physicians in that the patients received pampered care that ordinary NPTs would not. Further, the DCMs were not interested in clinical data but rather ensuring "good outcomes" to lead to more sales.

371. By way of example, Jennifer Minahan (who became Medtronic Diabetes District Clinical Lead), in response to questions regarding whether there were "best practices" for the COTs, provided the following instructions to DCMs on her entire team in an email dated September 1, 2010:

> 1. The DCMs should do the trainings to ensure good outcomes as we know we are way better trainers than our CPTs. I think it's up to you & Michael as to what makes sense for your business but my recommendation would be for the DCM to do the trainings so we can follow them and make sure that outcomes are good.
> ….
> 4. Best Practices. To be honest, I'm not sure it's been implemented yet. Mike and I would love to hear COT best practices as this is a GREAT tool that is not being implemented in our district. As a district we really need to step up here.

> There are territories that are killing their NPT numbers due to the COT...it works!!!

372. This email was forwarded to all of the Territory Managers in the District by District Manager Mike Ware, entreating them to use the Clinical Outcomes tracker ("COT") for patients new to therapy ("NPT") in order to sell the pump:

373. As a TM team need to get involved in the COT with our DCMs. There are TMs blowing it out there NPT because of the COT. Lets make sure that we are not asking for only 6 MDI patients...we need to ask for a minimum of 10 to 15. Lets get this implemented with our Big 3 and CAT accounts immediately. It is no additional work for our HCPs and they will have an opportunity to see the benefit of our technology for their patients.

374. By way of further example, after the current model of the pump, the PRT Revel, was approved by the FDA on March 17, 2010, Medtronic provided launch training and provided material referred to internally as the "Revel Yell." The Revel Yell identified two targets for the pump—patients with Type 2 diabetes and pediatric patients—and provided key selling points. Under a heading entitled "clinical evidence," it listed the "patient outcomes tracker."

c. Medtronic Misled Providers About the Lack of Clinical Findings of Safety and Effectiveness of U-500.

375. Medtronic used information from limited case studies and general references in journal articles to mislead providers that there was clinical studies to support the off label use of U-500.

376. To make physicians more comfortable with the idea of using U-500 in the pumps, the company instructed its sales representatives to provide their physicians with

journal articles that made positive references to pump therapy with U-500 insulin. One such article is by Dr. Steven Wittlin (an Medtronic Advisory Board member who receives paid incentives)[16] entitled, "Treating the Spectrum of Type 2 Diabetes: Emphasis on Insulin Pump Therapy.," The Diabetes Educator 2006 32: 39S, which states at page 43S:

> Although not approved by the Food and Drug Administration for use in pumps, U-500 insulin can be an alternative in patients who require very large doses. This concentrated form of insulin has been shown by Knee and colleagues in a case series to be effective . . . .

377. Sales representatives were also told to disseminate other articles that advocated use of insulin pump therapy for obese or insulin resistant Type 2 diabetics, such as, Wainstein, J. et. al, "Insulin Pump Therapy vs. Multiple Daily Injections in Obese Type 2 Diabetic Patients," Diabetes Med. 22, 1037-1046 (2005); Nielsen, S., *et al.*, "Use of Continuous Subcutaneous Insulin Infusion Pump in Patients with Type 2 Diabetes Mellitus," Diabetes Educator, November/December 2005, vol. 31 no. 6, 843-848. However, the Wainstein and Nielson articles did not present clinical data but rather were limited studies.[17] Sales representatives misrepresented these articles as clinical data to lead into a discussion with doctors about the treatment of their obese and insulin resistant Type 2 patients – patients that have traditionally been very difficult to treat, and that the sales representatives know will be put on U-500 insulin in the pump if pump therapy is initiated. Sales representatives use the information gained

[16] In his article emphasizing the use of Insulin Pump Therapy, Dr. Wittlin fails to disclose that he has served on the advisory board for and has received honoraria and grant/research support from Medtronic. *See,* K. Dugan, et al., *1,5-Anhydroglucitol and Postprandial Hyperglycemia as Measured by Continuous Glucose Monitoring System in Moderately Controlled Patients With Diabetes,* Diabetes Care, Vol. 29, No. 6, June 2006.

[17] Out of 40 patients in Wainstein's study, for example, only 29 finished. Further, only 15 were treated with pump therapy. Nielson only looked at 4 patients.

from these discussions to target the physicians' obese and insulin resistant Type 2 patients for pump sales.

378. By way of example, in September 2007, Diabetes Management Consultant Edward C. Stewart in Tacoma, Washington recounted his success in using the Nielson study (which only looked at 4 patients, 3 of which didn't finish the case study) to successfully convince a doctor to put a patient on the pump using U-500. The District Manager praised his efforts and circulated to the team and recommended the approach as using "clinical data to challenge a Prescriber's belief."

379. By way of further example, in November 2010, there was a regional conference call to review "Tips from the Top" for Insulin Pump Therapy for Type II Diabetes patients. Prior to the call, the Sales Director for the West Region, Michael DiGiulio, distributed a PowerPoint to be reviewed on the call. In introducing the topic as to "why" Medtronic's employees should focus on Type 2 patients, it noted there were 1.14 million Type 1 diabetics on insulin, compared to 4.18 million Type 2 diabetics on insulin. One slide highlighted suggested "Clinical Evidence" to review with doctors. Among the "clinical evidence" was the Neilson article. Another article the slide referred to as "Clinical Evidence" is by J. Wainstein, who engaged in a limited study. Finally, the slide suggested use of the Wittlin article on Type 2 patients. The slide did not identify, however, that Wittlin has received honoraria and gran/research support from Medtronic.

380. The Medtronic PowerPoint recounted the success story of a Dr. Gutin and noted that all three "clinical articles" were utilized to "emphasize better control & outcomes with CSII". The result was seven new Type 2 patients for the pump with two more "in the pipeline."

381. Medtronic provides a several-inch thick leather bound notebook called the "Site Seller" to its Territory Managers. The Site Seller is the product detail aid of choice from the corporate office and is used by sales representatives with healthcare providers and patients. One of the tabs is for treatment of Type 2 patients. Sales representatives use these slides on sales calls to promote use of the insulin pump with Type 2 patients, knowing that most of these patients, if put on a pump, will use U-500 insulin in the pump. The Nielson and Wainstein articles are prominently presented.

382. Medtronic also distributed a guide at a National Sales Meeting that provided speaking points regarding journal articles and instructed its sales representatives to provide their physicians with journal articles that made positive references to pump therapy with U-500 insulin or that discussed pump therapy for obese and insulin resistant Type 2 diabetics who, the company knew, would use U-500 insulin if they were placed on the pump. The Nielson and Wainstein articles were again prominently referenced.

d. Medtronic Misled Providers With a Bait-and-Switch -- Selling Providers on the Benefits of U-100 And then Promoting Use of U-500.

383. Medtronic sales representatives and other employees were trained to, and routinely did, misrepresent that U-500 was safe and effective for off-label use in the pump by falsely presenting U-100 benefits for Type 2 patients and then promoting the use of U-500 without disclosing that the benefits did not apply (instead, the use of U-500 elevated the risks).

384. One of the key selling points in converting Type 2 patients from MDI therapy to the pump was that the pump could use rapid-acting insulin instead of

intermediate or long-acting insulin. However, for Type II "insulin resistant" patients, Medtronic knew that the patient likely would need U-500, and, as discussed in detail above, regular acting U-500 has a slower time action profile than rapid-acting U-100 insulin. Thus, the territory managers employed "bait and switch" tactics, marketing the pump's efficacy by presenting materials regarding the benefits of using rapid acting insulin, then leading the physician to switching the patient to U-500, even though this was regular insulin that acted like intermediate insulin and off-label.

385. By way of further example, one of the homemade sales aids circulated throughout the Western Region was entitled "Which is Truly Easier?" It presents the idea that with the pump it is easier to eat a meal, by listing 5 simple steps necessary for the pump, versus 11 more complicated steps of MDI. The steps identified for the pump are:

1. Test BG
2. Count Carbs
3. Enter Carbs into pump
4. Push button to calculate entire bolus
5. Push button to deliver insulin

386. This sales aid was used to target Type 2 patients, who were generally viewed as being less compliant with recommended dosing regimens. However, the sales representatives also knew that the purportedly "easier" features of the pump disappeared with the use of U-500 insulin, which many of these Type 2 patients would be using.

e. Medtronic Falsely Represented to Providers that It Had Never Had an Over-Delivery of Insulin.

387. Medtronic also encouraged a message that its sales force routinely carried to patients and doctors, namely that Medtronic had never had an over-delivery of insulin. This was part of Medtronic's "safety message" and part of its core competitive message as to "why [choose] Medtronic" over a competitor during the entirety of Relator's employment with Medtronic. This was a national mantra and a message that Relator, other Territory Managers and Medtronic representatives had rehearsed many times.

388. By way of specific example, the Diabetes Management Consultant for Eastern Washington and Northern Ohio, Lisa Johnston, had a form letter to send to customers to convince them to buy a Medtronic pump over a competitor's product. In it, she writes:

> Medtronic Diabetes has been making insulin pumps for over 20 years. Within that time, over 30 different pump companies have come and gone - but we're still here. And in 20 years we have never had an over-delivery of insulin *-not one single time.*

(emphasis in original).

389. However, as outlined in this Complaint, Medtronic has had at least one adverse event reports filed with the FDA regarding over-delivery of U-500 insulin. Also, on July 10, 2009, Medtronic issued a recall for "Lot 8" Quick-set infusion sets, admitting:

> Medtronic recently discovered that approximately two percent of "Lot 8" Quick-set infusion sets (which represents approximately 60,000 infusion sets out of an estimated 3 million infusion sets currently with customers) may not work properly. The affected infusion sets may not allow the insulin pump to vent air pressure properly. This could potentially result in the device delivering too much or too little insulin and may lead to serious injury or death.

http://www.fda.gov/Safety/Recalls/ucm171588.htm.

f. Medtronic Misrepresented that Off-Label Use of U-500 Was a Nationally Accepted Practice.

390. Medtronic sales representatives and other employees were trained to, and routinely did, misrepresent that U-500 was safe and effective for off-label use in the pump by claiming that endocrinologists all over the country are using U-500 in the pump, which was not true when Medtronic began the promotion and misleads the provider into believing it is a nationally accepted practice.

391. By way of example, Relator and others were encouraged to use the Wittlin article to support their claim that this therapy was common, with remarks such as "look it's showing up in studies." The Wittlin article only remarked that U-500 insulin use in a pump "can be an alternative." Territory managers were also told by district and regional managers to state that "big dogs," or "key opinion leaders" (KOLs) in the diabetes community were using U-500 in the pump.

392. However, the spread of any practice of off-label use of U-500 use was created by Medtronic's own promotional practices, rather than by any national findings of the safety and efficacy of its use.

g. Medtronic Made Other Misrepresentations about the Efficacy of the Off-label Use of U-500.

393. Medtronic sales representatives and other employees were trained to, and routinely did, misrepresent that U-500 was safe and effective for off-label use in the pump by making claims as to efficacy with no clinical supporting evidence, such as claiming by being on the pump, Type 2 patients using U-500 could lose weight or claiming that diabetes easier to manage with U-500.

394. For example, the November 2010 “Tips from the Top” PowerPoint distributed by Michael DiGiulio presented a “DM2 Case Study” of a Medtronic I-pro client who had weight loss to support its claim that placing patients on a pump leads to weight loss. Territory Managers commonly referenced the Wainstien article as further “clinical” support that weight loss was common. However, as far as Relator is aware, there is no clinical supporting evidence that U-500 in pump therapy leads to weight loss.

395. By way of further example, a homemade detail aid circulated nationwide introduced an internet article from WebMD to use to sell against multiple daily injections for Type II diabetics. Sales representatives were told that this was a great conversation piece to get into a discussion about noncompliant type II diabetic patients whose diabetes was not well controlled. They discussed how these patients might be skipping their injections for economic reasons (insulin is paid for by Medicare if they are on the pump) or for convenience reasons (the insulin is not right there on the patient’s belt). This also led to discussion about U-500 insulin and the fact that often times patients who do take their insulin do not take more than 1 shot at a meal if they require more than 100 units because that would require more than one shot at one time.

396. Medtronic’s false and misleading representations about the benefits of off-label use were exacerbated by its fundamental failure to disclose to providers the significant health risks associated with the use of U-500. Medtronic falsely represented to prescribers, through its false statements and material omissions, that use of U-500 insulin with the pumps is safe and effective.

B. Medtronic's Scheme Resulted in False Claims to Government Healthcare Programs.

1. Causal Link to Claims Submitted to Government HealthCare Programs.

397. As alleged in more detail in Section I.C.1, *supra*, Medtronic knew that its practices resulted in claims to government healthcare programs, and that those claims were subject to the conditions of payment of those programs.

398. As a material condition of payment, only reasonable and necessary items and services are covered by government healthcare programs. A drug or medical device is not "reasonable and necessary" if it is not safe and effective.

399. Unlabeled uses of a drug are presumptively not safe and effective, and can only be covered in the circumstance that "the carrier determines the use to be medically accepted, taking into consideration the major drug compendia, authoritative medical literature and/or accepted standards of medical practice."

400. Medtronic is aware that U-500 insulin is not approved for use with the pump and that its use is not supported as safe and effective by any major compendia, authoritative literature, or accepted standards of medical practice.

401. Medtronic is also aware that its pump is not approved for use with U-500, and that there has been no safety and efficacy determination by the FDA, by CMS, or by any carrier of the off-label use of U-500 which it markets.

402. Medtronic is also aware that U-500 insulin is instead associated with significant safety risks, including FDA mandatory prescribing warnings about dosage confusion.

403. Notwithstanding those facts, Medtronic misleads providers through false

statements and material omissions that the use of its pump with U-500 is safe and effective.

404. Claims to government healthcare programs are the foreseeable, intended result of Medtronic's practices.

405. Medtronic knows that its actions are a substantial factor in the submission of claims for those government healthcare beneficiaries.

406. Medtronic is the only supplier of pumps promoting U-500 for this use. Moreover, Medtronic has significant control of the claims process. The provider's order and resulting certification of the medical necessity of each claim for the pump is based, at least in part, on Medtronic's representations about the safety and efficacy of its products, and on the underlying claims documentation it prepares.

407. Medtronic's false and misleading statements relating to the promotion of U-500 for off label use with the pump violate material conditions of payment of government healthcare claims, and would have the natural tendency to influence the government's decision to pay the resulting claims.

408. This conduct has been occurring since at least 2006 and is on-going.

409. Every claim submitted to the government (1) for a Medtronic insulin pump or (2) for U-500 insulin as a result of Medtronic's off-label promotional practices described herein constitutes a false and fraudulent claim in violation of the FCA.

2. <u>Representative Examples</u>.

410. As explained in Section I.C.2., *supra*, Relator was involved in the preparation of the underlying claims documentation for insulin pump orders, though the final claim for Medtronic's pump was processed by a different entity. However, claims

for U-500 insulin to be used in the pump was submitted by pharmacies pursuant to the prescription of each provider who ordered the pump. The use of U-500 insulin (claims for which are submitted by non-parties) was not consistently documented by Medtronic when completing its supporting claims documentation for the pump.

411. Relator personally observed that the practices described above resulted in false claims to government healthcare programs.

412. Relator was instructed to, and did, regularly promote use of U-500 insulin in pumps for Type 2 patients using the misleading message dictated by Medtronic. As a result of these corporately-directed practices, several of the doctors in his region, to include Drs. Gallen, Theen, Krishnamurthy, Radhakrishnan, Pardini, Carroll and McCarthy all prescribed U-500 insulin with the pump.

413. By way of example, Dr. Gallen initially would not prescribe the pump for Type 2 insulin-taking patients. Relator was instructed by Medtronic management to deliver off-label messaging to Dr. Gallen. District Manager Doug Villiers wrote Relator an e-mail message on April 15, 2008, regarding a planned field visit to Dr. Gallen:

414. Continue to focus on creative ways to challenge MD on T-2 (since he is against T-2, ask his challenges in treating patients on large doses of insulin. Run CGM on a few of these patients, and the results will lead you back into the pump discussion. When you review the tracings with Dr. Gallen, ask him the challenges he faces with getting these patients BG's lower? Ask him to explain further. Reinforce those challenges as "common" amongst his peers. Ask him exactly what steps he would take with that individual patient, and if that wasn't enough, then what? At that point, bring in the concept of breaking glucose toxicity, and the normal pancreas. This will lead you to

a T-2 trial).

415. As ordered by Medtronic, Relator provided Dr. Gallen with the U-500 prescribing information in January, 2010, even though Dr. Gallen had not requested such information. Dr. Gallen thereafter began prescribing the pump off-label, with off-label U-500 insulin for his patients, about a third of whom Mr. Witkin knew to be beneficiaries of government health insurance programs.

416. Medtronic convinced Dr. Krishnamurthy that pump therapy was the latest in treatment for her Type 2 patients who required large doses of insulin. Misleading sales messages were used. As ordered, Relator and other Medtronic employees misled Dr. Krishnamurthy by telling her that off label use of U-500 was safe and effective. They used, among other devices, the Anderson study (without disclosing that patients had been coached or that there were dosing difficulties with U-500 patients). They also made misrepresentations about the national use of U-500 and the potential benefit of reducing a patient's total daily dose over time (without disclosing the health risks or that Medtronic have developed the market for off label use).

417. A Call Planner dated 1/21/2010 included an Action plan for Dr. Krishnamurthy also discussed a "type II case study." The "[o]utcome" of presenting a Type 2 study to Dr. K was described as "[a]grees with who is ipro candidate. … Will bring MDI patients to the clinics for NPT."

418. Based on Medtronic's representations that U-500 insulin was the answer to the high insulin use of her Type 2 patients for whom she had previously prescribed pumps, Dr. Krishnamurthy was persuaded to initiate U-500 in the pump for any patient Medtronic suggested. Dr. Krishnamurthy thereafter began prescribing the pump off-

label with U-500 insulin. DR. Krishnamurthy's practice was between 33 to 40% government healthcare patients. One representative example of a claim resulting from false and misleading statements to Dr. Krishnamurthy is Medicare beneficiary JW, who participated in an iPro clinic on October 25, 2010, and subsequently was shipped a pump for use with U-500 insulin on or about January 24, 2011.

419. Further, after many paid lunches with Medtronic in which the same misleading promotional messages were delivered, Dr. Theen and his accompanying mid-level providers were persuaded to prescribe U-500 in the pump for their Type 2 diabetic patients. Relator recalls Medtronic referring a non-government beneficiary, initials MP, whose endocrinologist, Dr. Kelly, would not prescribe the pump off-label for use with U-500 insulin, but Medtronic was able to persuade Dr. Theen to prescribe it.

420. Consistent with Medtronic's corporate message, Dr. Radhakrishnan was falsely told that "everyone," particularly "thought leaders," were prescribing U-500 with the pump. She was persuaded to prescribe it for her patients (about a third of whom Relator knew to be beneficiaries of public health insurance programs). Medtronic Nurse Chris Makinson was initiating Dr. Radhakrishnan's pump referrals through iPro clinics, and carefully managing the patients on the pump, including U-500 patients, which gave a skewed view to Dr. Radhakrishnan of the ease of pump management for these patients. Makinson did the same with patients of Dr. Pardini, who was also persuaded to prescribe U-500 for use with the pump.

421. Medtronic representative also engaged in similar promotional practices with Dr. Carroll, who was also persuaded to prescribe U-500 for pump patients. For example, on April 5, 2010, Bend Memorial NP Tonya Koopman emailed Relator to start

the insulin pump approval process for patient NN. She noted: "He has severe insulin resistance and using U500 insulin." Dr. Carroll's practice comprised approximately 35% government healthcare beneficiaries.

422. This was a nationwide practice. For example, on September 26, 2007, Tacoma DCM Ed Stewart sent an email that Doug Villiers forwarded to Relator and several others, identifying a successful experience promoting off-label use of the pump for a Type 2 patient taking U- 500 insulin, including by presenting to a physician (Dr. Chen in Tacoma, Washington) the Nielson study, which did not in fact reflect a clinical determination regarding the safety and effectiveness of U-500. His misleading presentation resulted in a claim the next day for use of the pump with U-500 insulin for a Type 2 patient, a U.S. Postal Service employee publicly-insured by FHEB.

423. Representative examples of other providers who treat government healthcare beneficiaries and were targeted by Medtronic using these practices include PA John Nelson, in Eugene, Oregon; Dr. Kirk Jacobson, in Eugene, Oregon; and Dr. Richard Eddy, Medford, Oregon.

C. Medtronic Markets Its Adult Insulin Pump For Off-Label Use By Pediatric Patients.

424. Medtronic's Paradigm RT system is an integrated insulin pump and continuous glucose monitoring device. The FDA approved the Paradigm RT system for adult patients (ages 18 and older) on April 7, 2006 (Paradigm MMT-522 and MMT-722). The FDA approved a modified system for pediatric patients (ages 7 through 17) on March 8, 2007 (Paradigm MMT-522k and MMT-722k). This Medtronic pump is approved for pediatric patients ages seven through 17 (all other Medtronic pumps are adult only) and there is no pump or continuous glucose monitoring device approved for

children younger than seven.

1. Safety Implications for Pediatric Patients.

425. The insulin pumps in the Paradigm RT systems have alarms which alert the user when blood sugar levels rise above a high boundary, or sink beneath a low boundary. The difference between the adult and pediatric Paradigm RT systems is in the software settings in the pump for the alerts. The FDA required the pump in the pediatric Paradigm RT system to have more conservative settings for the low glucose alert than the pump in the adult system. The FDA insisted on this modification in order to provide pediatric patients with additional warning time to react to potential hypoglycemic (low blood glucose) episodes.

426. The following is the FDA's description of the difference between the adult pump and the pediatric pump in the Paradigm RT system (the letter "k" after a product number denotes that it is approved for pediatric patients):

427. The Paradigm MMT-522k and MMT-722k insulin infusion pumps are identical to the previously approved model MMT-522 and MMT-722 insulin infusion pumps (P980022/S013) with the exception of the programmable values available for the pumps' low glucose alarm. The minimum value that may be selected for the low glucose alarm for the MMT-522 and MMT-722 pumps is 40 mg/dL whereas the software used in the MMT-522k and MMT-722k pumps has been modified to limit the minimum programmable value for the low glucose alarm to 90 mg/dL.

428. In its approval memorandum, the FDA explained why it required a more conservative setting for the low glucose alarm in the pediatric pump as a condition for approval. The FDA explained that in Medtronic's pre-approval clinical studies with

pediatric patients, the glucose sensor in the Paradigm RT system provided higher readings than the reference meter (a fingerstick meter) at low glucose levels (levels below 80 mg/dL). Consequently, the FDA determined that it was necessary to set the minimum programmable values for the low glucose alert at 90 mg/dL (as opposed to 40 mg/dL in the adult pump) in order to "increase the probability that the device will alarm in the event of hypoglycemia when these devices are used by children and adolescents."[18]

429. Medtronic had complete knowledge of the risks attendant to setting the sensors too low in children. Its User Guide for the Paradigm Real Time Revel (2009 ed.), on page 231, discusses "Low and High alerts in children and adolescents." This section discusses a clinical study that evaluated the accuracy of the sensor component of the integrated system when used by children and adolescents. The Guide provides the following summary of the study:

> The Low Glucose Alert was evaluated for its ability to detect glucose levels at 70 mg/dL (3.9 mmol/L), or below, using the blood glucose meter. As a reference, with the Low Glucose Alert set at 70 mg/dL (3.8mmol/L), 24% (59/244) of low glucose events were detected by the Guardian RT. Better detection of low blood glucose can be obtained by setting the Low Glucose Alert level higher. For example, setting the Low Glucose Alert at 90 mg/dL (5.0 mmol/L), instead of 70 mg/dL (3.9 mmol/L), increases the ability to detect low blood glucose levels from 24% to 70%.

430. In other words, the device worked properly only 24% of the time to alert children or their parents that they were having a low glucose episode. This means that, most of the time, the device *never* alerted as the patient's blood glucose levels sunk

[18] FDA Approval Memorandum, "Summary of Safety and Effectiveness Data," March 8, 2007, at 6, available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cftopic/pma/pma.cfm?num=p980022s015

dangerously low. This statistic would be shocking to a parent or HCP if they were aware that Medtronic was selling pediatric patients an adult pump that can have the low blood glucose alert set at 70 mg/dL, as opposed to the minimum setting of 90 mg/dL on the FDA-approved pediatric pump.

431. The same data shows that if the low glucose alert is set at 90 mg/dL, as required in the pediatric model pump, the device detects low blood glucose episodes 70% of the time—a 180% improvement in effectiveness over the 70 mg/dL setting. Thus, the FDA approved the device as safe and effective for children with hypoglycemia detection factory-set at 90 mg/dL, but disapproved the standard pump.

432. Notwithstanding these actions by the FDA, Medtronic sells only its standard pump for pediatric use. By providing pediatric patients with the adult pump, Medtronic circumvents the FDA's safety requirements in order to reduce the number of annoyance alerts, but at the cost of reducing the device’s ability to alert the patient prior to a hypoglycemic event. Yet, it is precisely because the device can alert patients prior to a hypoglycemic event that patients use the device, doctors prescribe it, and insurers reimburse it.

433. In contrast to pediatric patients, the clinical study data for adults is better. When the low glucose alert is set at 90 mg/dL for adult patients, the low glucose episode detection rate is 82%, and at 70 mg/dL the detection rate is 49%. This makes clear why the FDA singled out children as requiring a separate device with more conservative settings. Simply put, the device is less effective in alerting children of low blood glucose episodes than it is adults. When Medtronic promoted the adult pump off-label to pediatric patients, it was disregarding clinical data, reported in its own User

Guide, showing that the alert settings in the adult device present a clear and known danger to pediatric patients. The sole motivation for Medtronic's conduct was increased profits, since Medtronic knew that the low blood glucose alerts in the pediatric model would be an annoyance and lead to increased attrition among users.

2. Medtronic Sells Only Adult Pumps to Pediatric Patients, to Preserve Sales and Customer Loyalty.

434. While the low glucose alarm setting in the pediatric pump provides an additional measure of safety, it also creates more frequent alerts. For Medtronic, this was a problem, because pediatric users and their parents complained that the setting was too conservative and resulted in so many alerts as to be annoying.

435. Medtronic did not want to lose customers because of this problem. Pediatric patients are the most valuable customers since they can be expected to be on diabetes products the rest of their lives. Also, parents are willing to buy the sensor for their child regardless of its cost if it will have any chance of normalizing their child's life.

436. Medtronic devoted considerable resources to promoting the efficacy of the Paradigm RT system for pediatric patients and achieve a pediatric indication – relying primarily on (1) a Medtronic-funded clinical trial involving pediatric patients called the STAR 3 trial and (2) a study done by the Juvenile Diabetes Research Foundation (JDRF) published in the New England Journal of Medicine in 2008,[19] both of which

[19] The JDRF writing committee responsible for this article includes the following doctors who have paid affiliations with Medtronic: Dr. Tamborlane who receives consulting fees from Lifescan, a partner with Medtronic and receives consulting and lecture fees and grant support from Medtronic; Dr. Bode who receives consulting and lecture fees, travel reimbursement and grant support from Medtronic; Dr. Buckingham who receives lecture fees and grant support from Medtronic and serves on an advisory board for Lifescan; Dr. Fiallo-Scharer who receives supplies for research from Medtronic; Dr. Hirsch, who receives grant support from Medtronic; Dr. Laffel who receives consulting fees from Lifescan and consulting fees and grant support from Medtronic; Dr. Weinzimer who receives lecture fees and travel reimbursement from

showed the efficacy of the Paradigm RT system for pediatric patients. The company did not want these efforts to be frustrated by the annoyance of the low glucose alert in the pediatric Paradigm RT system.[20]

437. In order to get around this annoyance which might flatten sales, Medtronic began selling the pediatric indications to interested providers and parents in the Paradigm RT system, but instead shipping the adult insulin pump instead of the pediatric pump (i.e., pump model numbers 523 and 723 instead of 523k and 723k).

438. This was consistent with Medtronic's previous practice of selling the adult pump to pediatric patients without an indication at all. For example, shortly after Medtronic received FDA approval for the Paradigm RT system for pediatric patients in March 2007, Medtronic also launched a new transmitter for the system called MiniLink. MiniLink made the product a lot more user friendly and thus received a big launch by Medtronic. As part of the launch, Medtronic provided a webinar session online for health care practitioners. One question and answer in the webinar addressed the simultaneous approval of the pediatric pump, showing that Medtronic was already actively selling the adult pump to pediatric patients:

> Q: Will pediatric patients have to upgrade to the "K" pump to use the CGM, or continue to use their 522/722 pump if they already have it and have been using CGM?
>
> A: Pediatric patients DO NOT have to upgrade to the K pump to use CGM. They should use whichever pump their doctor prescribes.
>
> If their doctor has already prescribed CGM for them and they are already successful on the standard model pump with CGM, there is no reason they need

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Medtronic; Dr. Wilson who receives equipment, software and grant support from Medtronic; and Dr. Wolpert who receives grant support from Medtronic.

[20] Further, Medtronic had to work against a competitive disadvantage in that its pediatric pumps did not as appear visually appealing to kids as its competitors' pumps.

> to change. If their doctor wants them to get on the K pump to use the CGM, then they would exchange their 522/722 for a 522K/722K for $299 when they buy the CGM Starter Kit.

439. Because diabetes treatment is so customized and individualized, we do not have a policy on what pediatric patients will by default receive. It all depends on the doctor's treatment goals and the doctor's prescription. We will fill the order and service whatever product the doctor prescribes.

440. In its Webinar Answer, Medtronic failed to include the fact that the FDA had found stricter controls necessary in the alerts to patients below the age of 18.

441. Medtronic strongly encouraged its sales representatives to invite all of the diabetes professionals with whom they had relationships to attend these webinars. Relator, for instance, routinely invited all of the providers in his territory, both physicians and diabetes educators, to attend. A large, national audience of healthcare providers viewed this webinar and was instructed that "there is no reason to change" a pediatric patient already on an adult pump to a pediatric pump.

442. Contrary to the Webinar Answer, when doctors prescribe the Paradigm RT system for their pediatric patients, the Medtronic sales representatives routinely order the system containing the adult pump. Due to Medtronic's successful false marketing of the adult pump, most health care practitioners are not even aware of the difference between the pediatric and adult insulin pumps.

443. Typically the ordering process works in the following manner. The doctor decides to prescribe a medical device (the Paradigm RT system in this example) for the patient. The doctor then tells the Medtronic representative to contact the patient. A Medtronic Territory Manager or DTC will call the patient and fill out a health

questionnaire based on the information the patient provides.

444. This health questionnaire is then given to a Medtronic DTA, who will verify the patient's eligibility for insurance benefits. The DTA then prepares a Certificate of Medical Necessity ("CMN"), sometimes called a Letter of Medical Necessity ("LMN"), which states that the device is medically necessary and that the patient meets the criteria for use of the device, and faxes it to the doctor's office for signature. Medtronic pre-populates the CMN to order the adult insulin pump, even if it is for a pediatric patient. Doctors, not knowing the difference between the model number for the adult versus pediatric pump, invariably sign the CMN, which is then submitted with all of the other insurance paperwork to the health plan.

445. Physicians rely on Medtronic representatives to assist them with the ordering process, and Medtronic pre-populates the paperwork to select the adult pump for pediatric patients, and does not inform them of the safety and efficacy issues presented by the adult pump.

446. Relator is informed and believes that, as a result of these practices, the vast majority of pediatric patients presently using a Medtronic insulin pump are using the adult insulin pump.

447. In his territory, for example, Relator is aware of no example where a pediatric pump was shipped to a pediatric patient. Moreover, Relator asked Medtronic DTA Michael Kim, an insurance specialist, what procedure a physician in his territory would follow to prescribe the pediatric pump. Mr. Kim, who at that time had been with Medtronic for approximately six years in several territories, replied that he did not know what that product was. This was remarkable because Mr. Kim is the person who

creates the LMN or CMN for the physician. By his response to Relator's question, Mr. Kim revealed that he was not even trained on what the pediatric pump was, let alone how to fill out the LMN or CMN for that product.

448. By selling the adult pump to pediatric patients in place of the pediatric pump, in order to bypass the more conservative low glucose alarm settings of the pediatric pump, Medtronic is circumventing the very condition that the FDA established for approval of the pediatric pump in the Paradigm RT system. Off-label sales of the adult pump to pediatric patients places these patients at increased risk of having hypoglycemic episodes – the very risk the FDA sought to avoid by imposing a lower alarm setting on the pediatric pump.

3. Medtronic Sales Representatives Were Not Trained to Sell the Pediatric Model.

449. Medtronic sales representatives visited provider offices with only the adult pump in hand, and were not trained regarding the pediatric pump. Relator, for example, never received any training on the pediatric pump, nor any internal practice sessions on marketing it.

450. Part of Medtronic's training to its sales force included helping representatives be able to explain to healthcare providers the ins and outs of ordering specific products, prescribing and billing insurance. Consequently, Medtronic's sales representatives were intimately familiar with product names, descriptions, and billing information. However, Relator was never trained how to describe to a physician the pediatric pump, much less how to prescribe the pump.

451. By way of further example, Relator is unaware of Medtronic's training guides for selling the integrated pump to pediatric providers ever addressing the

pediatric model. Instead, he received materials such as the "Revel Yell." In March, 2010, Medtronic launched the Revel product and provided the "Revel Yell" selling points for pediatric patients and patients with Type 2 diabetes. Among the selling points was that the product's predictive alerts were good for pediatric patients—that predictive alerts "catch it early." However, even the Revel Yell materials, which were distributed nationally by Sales Training Director Barbara Patterson and her team, made no mention of the *different* settings on the pediatric pump or that there is even a different pump approved for pediatric patients.

452. Further, Relator is unaware of any Medtronic sales representatives who used the pediatric model to demonstrate the benefits of an integrated pump at doctor's offices. Instead, the representatives routinely used the pump with the adult-default settings, even at pediatric provider's offices.

453. Moreover, the Guide that Medtronic developed and distributed nationally to practitioners of all patient types for its Paradigm Real Time System recommended setting up low glucose alerts at the adult setting - 70 mg/dl. Under the heading "Glucose Limits," and sub-headings "Considerations When Setting Low Glucose Alerts" and "Managing Low Glucose Limits," the recommendations state: "Setting Low Glucose Limits at 70 mg/dL will help to detect lows, but still limit frequency of alerts." Those this was distributed to providers of pediatric patients to support orders of the pump, this instruction plainly contravenes the FDA's safety requirement regarding the use of the pediatric pump with glucose alert settings no lower than 90 mg/dL.

454. Consequently, Relator and other Territory Managers did not sell the pediatric pump to their pediatric providers. They were trained to reference that

Medtronic's product had a "pediatric indication" in order to induce an order for a pediatric patient but they only physically sold the adult pump.

4. Medtronic Required its Representatives to Lie to Physicians, Telling Them That the Pumps of Competitors Were "Contraindicated" for Pediatric Use.

455. One of Medtronic's most misleading sales tactics was in its competitive messaging. In speaking with healthcare providers regarding the DexCom Seven PLUS product, Medtronic directed its sales force to reference as a "safety issue" that DexCom's product was contraindicated for pediatric patients. (Competitive Messaging Reference Guide). This was not true. Rather, *like Medtronic's adult pump*, the competitor's pump was not indicated for pediatric use. And the sales force were directed to reference the same "pediatric contraindication" as a "safety issue" when they spoke to health care providers regarding Abbot's Navigator pump. *Id.*

456. Medtronic instructed its sales force to market against its competitors with these statements. In printed materials distributed at Medtronic's FY2011 national sales meeting, called the "fight club" packet, the following talking points were provided regarding the competitor products:

> **FACT: This product is not approved for use in patients less than 18 years of age.**
> Q1: What percentage of your patients are under the age of 18? How beneficial do you think CGM is for your patients under 18?
> Q2: What benefits do you think CGM provides for your patients of all ages?

(emphasis in original). Medtronic sales representatives were expected to deliver this message about its competitors to providers without telling them that Medtronic was marketing its unapproved pump in exactly the same way.

457. These statements misled providers, as Medtronic's adult pump was not

approved for patients under 18, and there is no integrated pump approved for "all ages."

458. Thus, Medtronic's instructions to its sales force to make it a selling point that the REAL-Time product was the only product with a pediatric indication, even though they were selling the adult pump which did not have a pediatric indication, was false and misleading.

5. Medtronic Engaged in a Bait & Switch – It Would Market That its Pediatric Indication Lets Parents Sleep at Night and then Provide the Adult Pump.

459. Medtronic induced the ordering of pumps for pediatric patients by misrepresenting that it was a safe alternative for parents worried about glucose highs or lows in the night. Medtronic failed to disclose to providers and parents that it was actually only selling and shipping the adult pump to those pediatric patients.

460. By way of example, Medtronic routinely distributed an advertising packet to parents and doctors' offices entitled "Your Life. Your Way." Every office, clinic, or diabetes center that had been identified as a prescriber or a potential prescriber for pump therapy would have this packet in their office. The packet is replete with glossy pictures of children playing happily. It promises:

> When you add the [CGM] to your insulin pump …. You can see into the future. REAL-Time trend arrows help you avoid oncoming lows and highs before they happen. Stay in the game longer. CGM lets you personalize your insulin pump with high and low alarms so you get a heads up when it looks like you're going to be high or low.

461. The packet states "Medtronic has the first (and only) insulin pump with built-in CGM. You can see your blood glucose levels on your insulin pump every 5 minutes and it will warn you if you're about to go high or low." Conspicuously absent from the brochure, however, is an explanation that the pediatric pump and adult pump

have different warning settings—and that the FDA specifically disapproved the adult pump for pediatric use. Nor does Medtronic's literature reveal the risks attendant to use of the adult pump by children. In this packet, the only mention of the pump approved for children is in the footnotes on the last page of the brochure, in tiny font, where it states:

> MiniMed Paradigm insulin pump therapy can be used with or without continuous glucose monitoring and is approved for patients of all ages who have Type 1 or Type 2 diabetes. The Medtronic REAL-Time Continuous Glucose Monitoring System is approved for all patients aged 7 years or older who have Type 1 or Type 2 diabetes. It is available separately in 2 models: one for age 7 to 17 and one for patients 18 years and older.

462. This footnote does not provide the model number for the pediatric pump. Medtronic makes no effort to make it easy to differentiate the adult and pediatric pump. Rather, the brochure is replete with references to being the "only" integrated CGM device. Consequently, most parents did not know whether their child received the pediatric model or not.

463. Similar to above, Medtronic routinely distributed sales brochures to doctors regarding the benefits of using the "The world's ONE and ONLY integrated system" without educating the doctors as to the differences in indication between the pump models approved for adults and pediatric patients.

464. Another sales brochure extolled the benefits of "*REAL-Time Alerts* give patients peace of mind by helping them to minimize or avoid oncoming lows and highs. *NEW Predictive Alerts* can be set to warn your patients up to 30 minutes before their low or high glucose limits are reached. According to a recent internal study, the use of predictive alerts improved hypoglycemic event detection by 36% compared to the low glucose alert alone." The only mention of the pediatric model was in very tiny print: "A version of the product specially designed for children is indicated for patients age 7-17."

However, it does not provide the different model numbers or an explanation of the difference in the adult and pediatric versions.

465. The company's message to parents was that if their child was placed on the Paradigm Real Time system, they could rest assured at night knowing that the sensor will alert the parent or the child if the child's blood glucose drops below safe levels in the middle of the night. Most parents prior to using the device would have to wake up several times a night and take their child's blood sugar in order to guard against an extreme low in the middle of the night that could be life- threatening. Medtronic instructed its sales representatives to tell parents that once their child was put on the Paradigm Real Time system, they could sleep throughout the night without having to get up and check their child several times. Parents were told to put a baby monitor in the child's room and one in their room. If an alert went off, it would wake them up. No more sleepless nights. No more nights of constantly checking and of worrying. However, this was false and misleading, as with Medtronic's recommended alert settings on the adult pump, a parent will only be alerted in one of four hypoglycemic events.

6. Medtronic Used Other Misleading Promotional Materials to Induce Pediatric Pump Orders.

466. On January 24, 2011, Mike DiGiulio, Regional Sales Director for the Western Region, sent an email to the sales force in the West Region with the subject line, "4yr old giving Bolus - Add this to your iPad!" The email, which was marked "High" Importance, provided a link to a YouTube video showing a four year child using an insulin pump and glucose sensor. The email stated:

West Region Team,

> Wow, take a look at this powerful video. A 4 year old giving himself a bolus. Please add to your iPads team to use in your discussions with ped accounts. This speaks volumes about the simplest diabetes management system for patients . . . .
> http://www.youtube.com/watch?v=I-xWPEzNl_o&feature=youtube_gdata_player

467. The YouTube video is available for viewing at the above link. The text accompanying the video, written by the child's parent, explains that the child uses a Medtronic insulin pump and glucose sensor. Yet no version of Medtronic's pumps are approved for use in children under the age of 7.

468. Mr. DiGiulio referred to "iPads" in his email because Medtronic sales representatives now carry iPads into their sales calls to display promotional information on the computer screen. Medtronic encourages its diabetes sales representatives to use their iPads in creative ways to sell Medtronic's diabetes products. DiGiulio had previously given a presentation at the FY 2010 National Sales Meeting on "best practices to reach New Patients," and instructed sales representatives to place the following items, among others, on their iPads:

1. VOE [21]

2. You tube (*sic*)

3. Case Studies[22]

469. Sales representative's iPads were routinely used for off-label promotion. Like the YouTube video with the four-year old, none of these materials have been approved for marketing use by the FDA, and all of them frequently make off-label claims. Territory Managers presented these materials as "clinical evidence" to persuade

[21] The VOE refers to "Voices of Experience," which are testimonials of physicians.

[22] The "Case Studies" refer to homemade materials put together by sales representatives recounting experiences of their customers with Medtronic products.

healthcare providers and patients that Medtronic products were safe and effective.

470. By telling the sales representatives to add the YouTube video to their iPads, Mr. DiGiulio was instructing them to use the video on sales calls with physicians. Showing a physician or parent a video of a four year old using an insulin pump and glucose sensor misleads them into concluding that the pump is appropriate for use in children under 7 years old. This false and misleading off-label promotion of its pumps is not supported by any demonstrations of safety and effectiveness.

D. Medtronic's Scheme Resulted in False Claims to Government Healthcare Programs.

1. Causal Link to Claims Submitted to Government HealthCare Programs.

471. As alleged in more detail in Section I.C.1 *supra*, Medtronic knew that its practices resulted in claims to government healthcare programs, and that those claims were subject to the conditions of payment of those programs.

472. As a material condition of payment, only reasonable and necessary items and services are covered by government healthcare programs. A drug or medical device is not "reasonable and necessary" if it is not safe and effective.

473. Unlabeled uses of devices which are not supported by evidence of safety and effectiveness are not reasonable and necessary.

474. Medtronic is aware that its adult integrated pump is not approved for use by pediatric patients and that its use is not supported as safe and effective by any clinical trial, major compendia, authoritative literature, or accepted standards of medical practice.

475. Notwithstanding those facts, Medtronic misleads providers and parents

through false and misleading statements and omissions that they will be receiving pediatric pumps which are safe and effective for children of all ages.

476. Medtronic knows that its actions are a substantial factor in the submission of claims for those government healthcare beneficiaries.

477. Claims to government healthcare programs are not only the foreseeable, but the intended result of Medtronic's practices.

478. Medtronic's false representations and omissions regarding the safety and effectiveness of the use of its adult integrated pump by pediatric patients violate material conditions of payment of government healthcare programs, and would have a natural tendency to influence the Government's decision to pay the resulting claims.

479. This conduct has been occurring since at least 2007 and is on-going.

480. Every claim submitted to the government for a Medtronic insulin adult pump for a pediatric patient as a result of Medtronic's false and misleading off-label promotional practices described herein constitutes a false and fraudulent claim in violation of the FCA.

2. Representative Examples.

481. As explained in Section I.C.2., *supra*, Relator was involved in the preparation of the underlying claims documentation for insulin pump orders, though the final claim for Medtronic's pump was processed by a different entity. The claim for the insulin to be used in the pump was submitted by pharmacies pursuant to the prescription of each provider who ordered the pump.

482. Relator personally observed that the practices described above resulted in false claims to government healthcare programs.

483. Relator was instructed to, and did, regularly promote the adult pump for use in pediatric patients using the misleading methods identified above. As a result of these corporately-directed practices, Drs. Kelly, Lein, Cuddihy, Jacobson, Monchamp, McCarthy, Mendoza, Pardini, Michaels, Britsch, Bassett, Nelson (PA), Farmer all prescribed pumps to their pediatric patient population, which were each comprised of significant percentages of government healthcare beneficiaries. Relator knows, however, that no pediatric pumps were shipped in his territory, and that these orders were filled with adult pumps for these pediatric patients. In fact, when he queried his insurance specialist, DTA Michael Kim, Mr. Kim had no knowledge of a pediatric model.

484. By way of example, Dr. Noriecel Mendoza treated many pediatric patients along with adult patients in Medford, Oregon, and Relator marketed the adult pump to her both prior to and after the FDA approval. Relator marketed the Paradigm Real Time System to the office openly for both patient populations. That marketing resulted in many prescriptions of the adult pump to her pediatric population.

485. Similarly, Dr. Kelly's clinic had a large pediatric population. Dr. Kelly's enthusiasm for the data Relator presented for both safety and efficacy of the real time system (pump and real time sensor) led Dr. Kelly to prescribe many of those systems for his patients. Relator estimates that 25 percent of the pediatric patients at these practices were insured by Medicaid.

486. Dr. McCarthy was also a high prescriber. As a result of Medtronic marketing the integrated system with the methods described above, Dr. McCarthy prescribed the pump for his Medicaid patient, M.W., age 10, who was shipped an adult pump on July 7, 2009.

487. Following the launch of the pediatric pump, Medtronic DCM and relator conducted lunches to introduce the REAL TIME integrated system to the members of Bend Memorial Clinic's Pediatrics Department and to highlight the pediatric indication. As instructed by Medtronic management, he demonstrated the Low Glucose Alert, set at 70 mb/dl in the adult pump model, and the effectiveness of the alert, without informing them that this Alert was found to be less effective for pediatric patients when set at the this rate (using the recommended settings from Medtronic's User Guide). Dr. Cuddihy and RN Lein subsequently prescribed pumps to pediatric patients. Based on his familiarity with the practice, approximately 25% pediatric patients were on Medicaid, primarily COIHS. By way of example, on February 16, 2011, nurse Lein contacted Relator to refer a nine-year-old girl, Medicaid patient C.K., as a new pump patient. At the time of Relator's termination at the end of that month, the claims documentation was in the process of being completed. Based on the corporate pattern and practice for the several years before his termination, Patient C.K., in the ordinary course, would have been shipped an adult pump.

488. Relator followed the corporate message while marketing the REAL TIME integrated pump to Drs. Goldstein and Michaels, and they also prescribed a pump for a pediatric Medicaid patient, J.Y., shortly before his termination. Patient J.Y. had COIHS Medicaid insurance. Relator recalls that the case manager had approved the reimbursement but was terminated before it shipped. In the ordinary course, Patient J.Y. would have been shipped an adult pump.

489. Relator also promoted pediatric indications using the corporate messages at the Firehouse Diabetes Center to Dr. Michaels and PA Britsch. This was the main

office in Salem, Oregon for children with diabetes. Firehouse diabetes had a Medicaid population of approximately 30 percent of their pediatric diabetic patients.

490. Consistent with Medtronic's pediatric sales message, Relator promoted to Dr. Ravuri that Medtronic's product was indicated for pediatric use. Dr. Ravuri was excited about the indication, and sought to place an integrated pump on every child with Type I diabetes in his area, most of which were reimbursed by DOCS, the local Medicaid plan. By way of example, on February 2, 2011, an employee of Dr. Ravuri's, Alexis Weston, wrote Relator and requested: "Chris also mentioned that there is going to be a conference in Colorado regarding insulin pumps and Dr. Ravuri wanted to know if Medtronic sponsors attending these. We have two pediatric patients starting on pumps and if that goes well the peds dept. has twenty to twenty-five patients that they think would do well on pumps. Dr. Hannah that comes down won't start any of these patients on pumps because she is too far away to manage."

491. In Dr. Jacobson's office, Relator also followed management instructions and utilized the adult "dummy" pump to show Dr. Jacobson the effectiveness of the pump alert for a hypoglycemic event at 70 mg/dl. This demonstration was powerful and drove Dr. Jacobson to prescribe many PRTs for his pediatric diabetic population. What was not disclosed, however, was that the settings in the device he demonstrated had not been approved for pediatric use. Dr. Jacobsen therefore unknowingly prescribed the adult pump and Medtronic's DCM, Chris Makinson, trained Dr. Jacobson's patients using the recommended settings from Medtronic's Medical Director (which was in fact 70 mg/dl as the starting level).

III. FALSE CLAIMS RESULTING FROM INELIGIBLE AND MEDICALLY-UNNECESSARY ORDERS FOR PUMPS FOR TYPE 2 PATIENTS.

A. Compliance with Coverage Requirements Are a Material Condition of Government Healthcare Claims.

493. Medicare's coverage requirements are a material condition of payment of claims for Medicare beneficiaries. While Medicare provides coverage for certain items and services associated with the treatment of diabetic patients, coverage is subject to satisfaction of mandatory preconditions.

494. Medicare covers insulin-pump therapy only for beneficiaries with (1) Type 1 diabetes; and (2) Type 2 diabetes whose endocrine systems have lost the ability to make insulin. For such patients, laboratory results demonstrate that their insulin resistance mimics that of Type 1 sufferers. Medicare recognizes that the pump is effective for only those patients who have demonstrated effective self- management (such as regular blood glucose testing).

495. To evaluate these criteria, Medicare requires a documented fasting C-peptide (connecting peptide) level "that is less than or equal to 110 percent of the lower limit of normal of the laboratory's measurement method;" and a concomitant fasting blood sugar less than or equal to 225 mg/dl. (C-Peptides are created by the breakdown of the initial forms of insulin in the body, so C-peptide levels serve as a measure of the amount of insulin that the body makes.) Medicare Coverage Issues Manual, § 60-14 (September 2001); *see also* National Coverage Determination § 280.14 (February 18, 2005).

496. Medicare also requires that the following conditions be met before it will pay for an insulin infusion pump:

497. In order to be covered, patients must meet criterion A or B:

> (A) The patient has completed a comprehensive diabetes education program, and has been on a program of multiple daily injections of insulin (i.e. at least 3 injections per day), with frequent self-adjustments of insulin dose for at least 6 months prior to initiation of the insulin pump, and has documented frequency of glucose self-testing an average of at least 4 times per day during the 2 months prior to initiation of the insulin pump, **and** meets one or more of the following criteria while on the multiple daily injection regimen:
>
> > (1) Glycosylated hemoglobin level (HbAlc) > 7.0 percent
> > (2) History of recurring hypoglycemia
> > (3) Wide fluctuations in blood glucose before mealtime
> > (4) Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dl
> > (5) History of severe glycemic excursions.
>
> (B) The patient with diabetes has been on a pump prior to enrollment in Medicare and has documented frequency of glucose self-testing an average of at least 4 times per day during the month prior to Medicare enrollment.

Id. at § 60-14 (emphasis added).

498. Once these conditions are met, the pump must be ordered, and the patient's follow-up care must be managed, by a physician who manages multiple patients with insulin pumps and "who works closely with a team including nurses, diabetes educators, and dietitians who are knowledgeable in the use of [pump therapy]." *Id.* at § 60-14.

499. Other government insurance programs follow similar pre-conditions for payment of insulin pump therapy. Though the majority of beneficiaries at issue are Medicare beneficiaries, Medicaid also provides coverage for the insulin pump under similar or stricter conditions (several states, for example, only cover pumps for Type 1

diabetics).[23]

500. Claims submitted, or caused to be submitted, in knowing violation of these conditions of payment are false claims in violation of the FCA.

B. Medtronic's Push For Type 2 Patients on the Pump.

501. Medtronic's corporate strategy was focused on "expanding indications" for its insulin pump, and breaking into the Type 2 market as a replacement for conventional injection therapy for insulin-dependent patients.

502. However, as described above, government healthcare programs only cover infusion pumps for a very limited subset of Type 2 patients who satisfy "strict criteria" of eligibility, including minimum ranges on a C-peptide test (which measures insulin levels through the presence of peptides, which are by-products of insulin synthesis). CMS Decision Memo for Insulin Pump: C-Peptide Levels as a Criterion for Use (CAG-00092R) at 19 (Dec. 17, 2004).[24] These requirements are difficult to satisfy for the majority of Type 2 patients.

503. Because the strict coverage limits restrict sales of its pump to large numbers of Type 2 patients, Medtronic requested in 2004 that CMS remove the C-

[23] The States of California, Georgia, Louisiana, and Minnesota cover insulin infusion pumps only for recipients with Type I diabetes that meet certain additional requirements. The States of Montana, Michigan, Nevada, North Carolina, and Oklahoma, have regulations which substantially mirror Medicare regulations for reimbursement of insulin infusion pumps. The States of Colorado, Connecticut, Delaware, Florida, Hawaii, Illinois, Indiana, Maryland; Massachusetts; New Jersey; New Mexico; New York, Rhode Island, Tennessee, Texas, Virginia, Wisconsin, and the District of Columbia require Prior Authorization and a determination of medical necessity for reimbursement of insulin infusion pumps. *See* Providing Diabetes Health Coverage: State Laws and Programs, National Conference of State Legislatures (May 2011) (compiling program requirements) (available at http://www.ncsl.org/issues-research/health/diabetes-health-coverage-state-laws-and-programs.aspx).

[24] Available at http://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=109&NCDId=223&ncdver=2&NcaName=Insulin+Pump*3a%24+C-Peptide+Levels+as+a+Criterion+for+Use&IsPopup=y&bc=AAAAAAAACAAAAA%3D%3D&.

peptide testing as a criterion for coverage of insulin pumps. In its request, Medtronic identified that hundreds of Medicare patients per year failed to meet the C-peptide criteria.

504. After careful analysis of the clinical evidence, CMS rejected the suggestion that it should relax its standards for coverage of insulin pump therapy. The agency issued a detailed Decision Memo explaining its coverage decision. The Decision Memo states that the majority of elderly diabetics who are government healthcare beneficiaries suffer from Type 2 diabetes, and that there is a lack of clinical evidence regarding the use of insulin pumps in that population. CMS Decision Memo at 13.

505. CMS concluded, based on the consensus of the literature and review of expert opinions, that the "*use of the [insulin pump] is rarely indicated* in [Type 2 patients] and that strict criteria should be used for eligibility." CMS December 17, 2004 Decision Memo at 19 (emphasis supplied), *citing*, *e.g.*, NICE Technology Assessment and Aetna Clinical Policy Bulletin #0161.

506. Undaunted by its failed attempt to legally expand the coverage of the insulin pump by government payors, Medtronic established a national sales strategy to expand its sales of insulin pumps to the Type 2 market without regard to CMS's decision.

507. Medtronic was tightly focused on converting MDI patients (traditionally Type 2 patients) to pump therapy. It wanted to increases its new pump patient sales (referred to as NPT) and gave sales representatives minimum requirements regarding their conversion of NPT's per month.

508. As illustrated on its "Therapy Driver Account Profile," a training material reflecting what Medtronic taught its personnel as "best practices:" "For an account to maximize its potential, it must understand and believe in all of the indications of pump therapy, promote the therapy to *all insulin requiring patients*, and *not limit the therapy to specific patient types*." Emphasis added. Medtronic also states that one of its end goals is that "HCP [healthcare provider] promotes IPT [insulin pump therapy] as the standard of care for *all insulin-requiring patients*." (Emphasis added) (Therapy Driver Account Profile).

509. In another email dated October 2009 describing purported "best practices," District Manager Ware states: "***Expand Indications.*** Type II is a very large, under-served segment…" and regarding iPro clinics: "focus on indications with the HCP, not just a single patient." (October 15, 2009 Email from Travis Allen with Subject: NPNP Best Practices (emphasis supplied)).

510. So, even as Medicare mandated that pumps were "rarely indicated" for Type 2 diabetics, Medtronic sought to convince the medical community that the pump should be prescribed for *all* Type 2 patients.

511. Medtronic directed its sales force to "expand indications" in the Type 2 market through myriad means. As described in Section I above, Medtronic induced providers to promote pump therapy for all their patients, through the use of paid incentives. As described in Section II above, Medtronic used misleading sales aides, sham clinical studies, and anecdotal examples to dupe physicians into expanding the indication for pump therapy into their MDI patients. For example, Medtronic ginned up "studies" of small groups of patients coached those patients into perfect compliance by

Medtronic; and used the resulting "data" convince physicians that all Type 2 patients would have achieve similar results.

512. Once Medtronic procured buy-in from the provider to order an insulin pump for a Type 2 patient, Medtronic guaranteed the sale by coaching patients to manipulate their insulin levels in order to meet federal criteria for reimbursement. Because Medtronic controlled the process for preparing the underlying claims documentation, it was able to elicit and provide false information to providers and government healthcare programs to support claims for insulin pumps.

C. Medtronic's Misrepresentations Regarding Type 2 Eligibility.

513. While Relator worked for Medtronic, it was routine practice for Medtronic to prepare or cause preparation of false statements and records certifying that patients meet these eligibility criteria when they do not in fact meet the criteria.

514. Medtronic has the opportunity to engage in this misconduct because it typically assists patients in submitting applications for insurance coverage of Medtronic products. Most patients sign an "Authorization/Assignment of Benefits" form that authorizes Medtronic to submit patient information to the insurer.

515. To gather relevant patient information, Medtronic requires patients to fill out a health questionnaire providing sufficient information to verify that the patient satisfies the criteria for eligibility under the Medicare Guidelines. (Medtronic Confidential Health Questionnaire). Patients rarely fill out the questionnaire on their own. They are encouraged to contact a Medtronic sales representative or call Medtronic's 24 hour telephone center helpline to assist them in filling out the questionnaire. The telephone helpline is staffed by Medtronic Diabetes Therapy

Consultants ("DTCs") and Diabetes Therapy Associates ("DTAs").

516. A Medtronic representative typically fills out the health questionnaire while speaking with the patient, either in person or by telephone, and gives it or faxes it to the patient to sign. In the rare instance in which the patient fills out the health questionnaire on his or her own, Medtronic's practice is to contact the patient to ensure the questions are answered in an optimal manner to receive insurance coverage. The health questionnaire is easy to change because it has no space for a signature by the patient; therefore it can be revised any number of times without resubmitting it to the patient for a new signature. The only document that the patient signs is the Patient Information Authorization and Assignment of Benefits form, which is on a separate sheet from the health questionnaire.

517. Medtronic submits the health questionnaire together with the AOB to the contractor engaged by Medtronic to submit claims to the relevant insurers. The contractor then pre-populates a Certificate of Medical Necessity (sometimes called the Letter of Medical Necessity) certifying that the device is medically necessary and that the patient meets the criteria for use of the device, and faxes it to the doctor's office for signature.

518. Most MDI patients cannot meet the Medicare requirement that they have a "documented frequency of glucose self-testing an average of at least four times per day during the two months prior to initiation of the insulin pump." "Documented" means documented in the patient's medical records or chart notes.

519. Medtronic sales representatives and helpline staff are trained in techniques to elicit from patients the statement that they meet the self-testing

requirement even when they do not. There are many such techniques. For example, the patients are told that they will only obtain insurance coverage if they answer "yes" to certain questions, and they quickly get the picture and provide the "right" answer. Because the health questionnaire is not signed, patients are generally willing to go along with this charade and provide the "right' answer even when they know it is false. Some Medtronic representatives answer the questions without even asking the patient. Because the sales representatives have generally already met with the patient, they are aware that the patient is not compliant with the testing regiment required by government healthcare programs.

520. Medtronic also trains all of the CPTs, diabetes centers, nurses, and medical assistants that do business with Medtronic in these same interview techniques. They generally comply because they get paid by Medtronic when a pump sale is made (for example, by receiving training fees, see section VI.B.1 *supra*); and of equal importance, if the answers are wrong and insurance coverage is denied, it will be their responsibility to appeal the determination and gather the necessary documentation, as well as deal with their frustrated patient.

521. One reason this fraudulent scheme works so well with Medicare is because Medicare does not require prior authorization to approve an insulin pump. Medicare relies upon the certification of the physician that the patient meets the eligibility criteria. The physician, in turn, relies on Medtronic, who has prepared the underlying documentation.

522. In contrast to Medicare, many other insurers require Prior Authorization before covering an insulin pump. As part of the approval process, these insurers

routinely check the patient's underlying medical records to determine if the patient has a documented record of self-testing glucose levels four times a day. In Relator's territory in Oregon, Medtronic has a very low success rate, much less than 50%, in getting coverage for the pump when an insurer requires Prior Authorization and checks for documentation of self-testing.

523. In December 2010, Relator's Manager, Mike Ware, sent an email to the sales force in the Pacific Northwest District directing them that they needed to change their practices when submitting information to the private insurers that require Prior Authorization. Mr. Ware's email is telling because it does not require Medtronic representatives to change their practices in regard to public or other insurers which do not require Prior Authorization (such as Medicare). The email states:

> The reason for this email is to provide you insight on how our DTA counterparts will be handling the PA [Prior Authorization] process for Regence (WA & OR), Premera [sic.], and First Health. We have received several denials for RTS [the Real-Time System insulin pump] over the past few months. The denials have been a result of documents (office notes, bsl [blood sugar level], hypo events [hypoglycemic events]) not matching the LMN [Letter of Medical Necessity].
>
> Protocol for Regence of WA, Regence of OR, Primera and First Health:
> - Request office notes and BSL (Fax 1)
> - Compile LMN with accurate information
> - Request signature of LMN (Fax 2)
> - Submit for Prior Authorization

(December 6, 2010 Email from Mike Ware with Subject: RTS-IMPORTANT) (emphasis added).

524. No attempt was made to change the company's protocol with regard to Medicare, because it rarely conducts an audit to verify the submitted information. Medtronic's practice with Medicare was, and continues to be, to falsify the information

submitted to Medicare in order to qualify MDI patients for insurance coverage for pump therapy.

525. Medtronic also coaches patients on how to falsify the results of their fasting C-peptide test. C-peptide is a byproduct created when the hormone insulin is produced by the pancreas. The C-peptide test is an indicator of how much insulin is being produced by the pancreas.

526. As noted, Medicare Guidelines require that the patient's "[d]iabetes needs to be documented by a fasting C-peptide level that is less than or equal to 110 percent of the lower limit of normal of the laboratory's measurement method." The C-peptide level that is less than or equal to 110 percent of the lower limit of normal is typically a C-peptide level at or below 70 or 80 ng/mL (nanograms per milliliter).

527. After its campaign to convince CMS to remove the C-peptide requirement from the Medicare Guidelines failed, Medtronic began coaching its customers in methods to produce low C-peptide test results in order to meet the Medicare Guidelines.

528. The first method that Relator was taught, by his manager at the time (Doug Villiers), was to instruct patients to go on a carbohydrate fast for several days before the C-peptide test. Relator felt pressure from his manager to follow this instruction and therefore did so.

529. Medtronic sales representatives had considerable success with this technique. Based on Medtronic's widespread promotion of the technique, Relator observed that the majority of sales representatives and diabetes educators in his District were routinely using this technique to support claims for pumps.

530. Relator was also instructed on another method to manipulate the C-

peptide test at Medtronic Minimed's headquarters in Northridge, California, during a Customer Visit Program. Managers from across the country were at the meeting.

531. During the meeting, Rudy Thoms, a District Manager in the Michigan area, told the assembled group of a "foolproof" method that he had been using for a long time. Mr. Thoms explained that the method involves inducing hypoglycemia, since a C-peptide test during a hypoglycemic episode will always be well below normal because there is no insulin production at that time (and therefore no C-peptide production), even in a normal pancreas.

532. Mr. Thoms explained the method in detail. Patients are instructed to go to the testing lab, and while there inject themselves with an overdose of insulin. Then the patients self-test their glucose level to confirm hypoglycemia, and then take the blood draw for the C-peptide test, which invariably will show a C-peptide of less than 1.1 times normal levels. The patients stay in the testing facility drinking a juice box until blood glucose levels come back up to a safe level.

533. Mr. Thoms told Relator that the company had been coaching patients and providers on this method for some time. Mr. Thoms has since been promoted to a managed care position within Medtronic.

534. Relator also learned about this same technique from Mike Ware, who became Relator's District Manager in July 2010. Before assuming that position, Mr. Ware had been a Territory Manager in Colorado. Mr. Ware told Relator that getting a pump candidate to pass the C-peptide test was a "piece of cake". He instructed Relator to do exactly as Mr. Thoms had instructed Relator a few years earlier.

D. Medtronic's Scheme Resulted in False Claims to Government Healthcare Programs.

1. Causal Link to Claims Submitted to Government HealthCare Programs.

535. As alleged in more detail in Section I.C.1 supra, Medtronic knew that its practices resulted in claims to government healthcare programs, and that those claims were subject to the conditions of payment of those programs.

536. Indeed, as described above, Medtronic actively lobbied CMS to relax its requirements for government healthcare beneficiaries. Medtronic is well aware of the challenges associated with government payor reimbursement of its products, including Medicare's preconditions for coverage of insulin pumps. One Medtronic presentation entitled "Insulin Pump Therapy for Type II patient" referred to these coverage issues as "The Elephant in the Room."

537. Government healthcare programs restrict coverage of pump therapy to only those patients who meet the specified eligibility requirements. Government healthcare programs also restrict coverage of medical devices to those that are reasonable and necessary. Claims for medical devices are not reasonable and necessary when they are not safe and effective, exceed the patient's medical need, or serve essentially the same purpose of equipment already available to the beneficiary.

538. Failure to satisfy these requirements violate material conditions of payment for government healthcare programs and would have a natural tendency to influence the Government's decision to pay the resulting claims.

539. Claims to government healthcare programs are not only the foreseeable, but the intended result of Medtronic's practices.

540. Medtronic knew that its actions to skew laboratory results and falsely document patient eligibility were a substantial factor in the payment of claims for government healthcare beneficiaries.

541. Medtronic also knew its false statements regarding the safety, efficacy, and/or need for a Type 2 patient to convert from MDI therapy to pump therapy were a substantial factor in the resulting orders for pump therapy.

542. For example, a December 6, 2010 email from the District Clinical Lead in the Pacific Northwest region described a success story to the District Manager and other sales representatives:

> This is a new prescriber endo in Medford that Chris and I called on last week. When Chris approached Type 2s and insulin pump therapy with her on Wednesday she said she had never considered the pump for them as they are all labeled non-compliant and she thinks they need to be proving themselves before they are offered the pump. She also stated that she has never not been able to get a Type 2 under glycemic control with orals and MDI. Just two days after Chris called on her she referred her first Type 2 and is also keeping a list of patients for an upcoming iPro clinic.

543. Medtronic's false statements to providers and in the underlying claims documentation are material to payment of the resulting claims for government healthcare insurers.

544. This scheme has been occurring since at least 2004 and is on-going.

545. Each claim for reimbursement of an insulin pump and insulin for a government-insured Type 2 patient caused by Medtronic's fraudulent conduct constitutes a false claim in violation of the FCA.

2. Representative Examples of Ineligible and Unnecessary Claims.

546. As explained in Section I.C.2., *supra*, Relator was involved in the

preparation of the underlying claims documentation for insulin pump orders, though the final claim for Medtronic's pump was processed by a different entity. The claim for the insulin to be used in the pump was submitted by pharmacies pursuant to the prescription of each provider who ordered the pump.

547. Relator personally observed that the practices described above resulted in false claims to government healthcare programs.

548. Relator was instructed to, and did, regularly coach patients to do carb fasting to cheat the c-Peptide test to help Type 2 patients falsely qualify for medical necessity coverage of the pump, and is personally aware that this was a Medtronic direction used regularly by sales representatives. As a result of these corporately-directed practices, Drs. Krishnamurthy, Radhakrishnan, Carroll, Theen, Eddy, McCarthy, Huang, and Michaels all used this method.

549. As discussed above, Relator learned this method from his then-manager Doug Villiers. Soon after, he was approached by RN and Certified Diabetes Educator Sue Amidon and physician Chuck Huang regarding a patient who had failed his first c-Peptide test. This patient had received a pump while on private insurance, but was currently on Medicare and needed to pass the c-Peptide in order to continue pump therapy. His first c-Peptide test was nearly double the allowable value Medicare approved. Relator passed on his manager's instructions regarding the carb fasting and patient GD was able to pass the c-Peptide test the in his second attempt. His pump was shipped on July 28, 2008. This was Relator's first success story with carb fasting and it became part of his sales message moving forward for all Medicare patients with Type 2 diabetes and their providers.

550. Further, Relator in teaching this method to RN CDE Amidon, the carb fast cheat was able to spread to the Institute of Diabetes and Endocrinology and this technique was used to help Medicare patients of Drs. Kelly, Eddy and Hungeford qualify for the Medtronic insulin pump. Relator specifically recalls Drs. Michaels and McCarthy also had patients utilize the carb fast cheat to successfully qualify for pumps, as well.

551. By way of further example, PA Gina Jones, who worked for Dr. Theen, contacted Relator on November 15, 2010 regarding a patient who needed supplies for her pump but did not meet the qualifications for c-Peptide. She wrote that she recalled "you recommending a low-carb diet for 3d before test, and that might drive the c-peptide down?" Relator shared the carb fasting technique with all of his providers who prescribed the pump to Type II patients.

IV. MEDTRONIC ACTED KNOWINGLY.

552. At all times relevant to this action, Medtronic knew that the reasonable and foreseeable consequence of its schemes would be the submission of false claims to government healthcare programs and that payment of such false claims would result.

553. As demonstrated in Sections I.C, II.B & D, and III.D, *supra*, Medtronic knew that its targeted providers treated government healthcare program patients, knew that its schemes resulted in increased sales of its insulin pumps, and knew, based on its interactions with patients and its role in preparing the underlying claims documentation claims, that claims were submitted to government healthcare programs for insulin pumps, for insulin used in those pumps, and for associated professional services billed by the targeted providers.

554. Medtronic knew that its practices were in violation of material conditions of

payment of government healthcare programs, including because: (1) it was not in compliance with the AKS and Stark laws while it was submitting, and causing the submission of, claims; (2) it provided false and misleading information to providers regarding the safety and effectiveness of the off label use of its products; and (3) it made false statements to providers and government healthcare programs about the eligibility of Type 2 patients for coverage of insulin pump therapy.

555. Medtronic intended that claims for items and services relating to its diabetic products be paid by government healthcare programs

556. Medtronic's actions were a substantial factor in the submission of false claims.

557. Medtronic's conduct, if known, would be capable of influencing the government's decision to pay these claims.

558. Notwithstanding this knowledge, Medtronic submitted false claims for insulin pumps for government healthcare beneficiaries and caused false claims to be submitted to government healthcare programs for the insulin to be used in those pumps and for the professional services associated with professional GCM and pump therapy provided to patients of targeted providers.

559. Medtronic has made no effort to identify and return overpayments related to these claims.

560. Medtronic's schemes are corporately-directed and nationwide in scope.

561. Medtronic's conduct has harmed federal and state healthcare programs.

V. MEDTRONIC UNLAWFULLY RETALIATED AGAINST RELATOR.

562. Relator was terminated by Medtronic on February 28, 2011. For the six years between his hiring in 2004 and 2010, Relator was promoted, received high performance reviews, and was recognized for his excellent sales results. In the space of 5 months after he first reported his concerns with Medtronic's practices, including what he believed to be kickback schemes, he was reprimanded, written up, harassed, and then fired. As explained in more detail below, Relator observed conduct that reasonably could lead to an FCA claim, including potential kickback violations. He first reported his concerns to his District Manager. When that did not result in changed behavior, Relator tried to stop what he in good faith believed to be fraud and abuse by reporting his concerns to the FDA, the local medical board, and to Medtronic's corporate offices. Within weeks of notice to Medtronic corporate representatives of his protected activity, including his concerns about kickback practices, he was terminated. As identified further below, Relator alleges that his termination was wrongful under federal and state law.

563. Relator was a longstanding and loyal employee of Medtronic who consistently achieved excellent sales results in the course of over six years of employment in the Company's diabetes division. He was recognized as a top performer via his promotion in June 2007 to the rank of Senior Territory Manager, his selection in June 2007 to Medtronic's President's Club, and his designation in May 2010 as a National Field Trainer in addition to the performance of his duties as a Senior Territory Manager. Relator never received anything less than a rating of "successful contributor" on his performance reviews and often achieved the higher or highest-allowed

performance rating. Medtronic believed in Relator's skills and value to the company so strongly that it paid for him to get his MBA and Master's in Science and Strategic Management. Relator accomplished this while working full time as a Territory Manager and later as a Senior Territory Manager.

564. Although Relator's sales work was based in Oregon, throughout the entirety of his employment, Relator had frequent contact with MiniMed's corporate headquarters in California. Approximately twice a year, Relator brought customers to the California headquarters for special sales calls called "Customer Visits." Relator participated in multiple conference calls run from the California headquarters, including: monthly national sales calls run by Mike Gill; "Greg's Huddle" calls, which were periodic conference calls about Medtronic performance and outlook run by Gregory Meehan, then-Vice President of Sales; and product training calls run by corporate staff. Relator also conferred by telephone multiple times a day with the Diabetes Therapy Associate assigned to assist him, who was located in California.

565. As a Senior Territory Manager, Relator worked under the immediate supervision of a District Field Manager. During July 2010, Medtronic assigned Mike Ware as Relator's District Field Manager and Mr. Ware remained Relator's District Field Manager through the date of Relator's termination. Among Mr. Ware's foremost concerns as District Field Manager was his team's aggressive use of iPro clinics to enhance sales of pump therapy to MDI patients eligible for reimbursement variously through Medicare, Medicaid and private insurance in line with the marketing program described above.

566. Prior to July 2010, Relator had utilized the assistance of his DCM to

handle medical aspects of the iPro clinic procedure including insertion of the iPro sensor under the patient's skin via insertion of a large needle. Relator had been outspoken in his sales district about not conducting iPro clinics and inserting needles on his own. Relator's manager at the time, Travis Allen, had accepted Relator's practice and had not pressured him to perform the iPro clinics himself. Accordingly, Mr. Ware was aware of Relator's practice in that regard when he became Relator's District Field Manager. Beginning in July 2010, Mr. Ware directed Relator to handle the iPro procedure alone, without the assistance of his DCM who was an RN, because Medtronic wanted the sales representatives to be the main point of contact with the patients. Since Relator believed doing so constituted the performance of a medical diagnostic procedure, despite Mr. Ware's direction, he continued to have his DCM perform the procedure.

567. As District Field Manager, Mr. Ware supervised Relator's work through periodic field rides, which involved accompanying Relator on visits to the offices of physicians in his territory through whom Medtronic marketed its insulin infusion pump and other products. Relator had his first field ride with Mr. Ware on September 28 and 29, 2010, during which there were no iPro clinics scheduled, yet the primary focus of their discussions was on the performance of iPro clinics.

568. During the September 28-29, 2010, field ride, Mr. Ware directed Relator that, when he performed the iPro clinics, he needed to do them himself rather than having his DCM perform the procedures. Relator objected to this direction stating that he had no legal or business certification that qualified him to perform any medical diagnostic procedure. Disregarding Relator's concern, Mr. Ware insisted that it was necessary for Relator to perform the iPro clinics by himself – without either his DCM or

physician's staff members being present – in order to maximize the opportunity to sell patients on pump therapy and simultaneously free up the physician's staff.

569. During the September 28-29, 2010, field ride, Mr. Ware also instructed Relator to show physicians Medtronic's economic model and to tell them how much money they could make by billing for staff time during his meetings with them. Relator objected that providing physicians with a service which they did not perform but for which they could claim payment "sounded like a kickback" to the physicians. Mr. Ware responded in a visibly irritated manner and instructed Relator to follow his directions notwithstanding Relator's concerns about the legality of Mr. Ware's instructions.

570. Mr. Ware was clearly displeased with Relator's insistence that it would be improper for him to perform iPro clinics without the assistance of medical personal and his expressed concerns about engaging in a marketing scheme with physicians that improperly incentivized physicians by providing kickbacks. Consequently, at the end of the field ride, Mr. Ware gave Relator low field-ride ratings of 1 and 2 out of 5 in most categories, even though Relator had achieved top results in the district for sales of pump therapy.

571. In response to Mr. Ware's pressure on Relator to perform iPro clinics alone in order to maximize the sales of Medtronic pump therapy to MDI diabetes patients, Relator sought to memorialize Mr. Ware's instruction. By email to Mr. Ware dated October 14, 2010, Relator summarized Mr. Ware's instructions regarding Territory Managers performing iPro clinics in the respective physicians' offices on a weekly or biweekly basis indefinitely. In the email, Relator documented that Mr. Ware wanted him, as a Territory Manager, to sell iPro patients on pump therapy while he hooked up

and downloaded Medtronic's sensor device and that his conducting the iPro clinics would benefit the physician by freeing up his office staff. Mr. Ware responded: "You have a solid plan. Now it is about executing on the plan."

572. Relator repeatedly expressed reservations to Mr. Ware about being required personally to insert needles and to remove the needle leaving the glucose sensor secured under the patient's skin. Relator objected both because insertion of the needle to hook up the device is a medical procedure which he was not qualified to perform and because insertion of the needle in two of the recommended sites – the upper pubic and upper buttocks areas – posed a gross invasion of the patient's privacy, particularly when the patient was of the opposite gender, and posed a medical risk to patients. On the occasion of the first field ride and thereafter, Mr. Ware forcefully rejected Relator's concerns and directed him to do the procedures himself under threat of being fired if he did not.

573. Mr. Ware accompanied Relator on a second field ride on October 25, 2010 which involved visits to the office of Dr. Priva Krishnamurthy and to Providence Diabetes Center. Knowing that Dr. Krishnamurthy routinely permitted Medtronic to run the iPro clinics without any involvement by her staff, Relator had asked his DCM to participate in the October 25, 2010 clinic in order to handle all of the medical aspects. When Mr. Ware realized that the DCM was participating in the clinic, he strongly criticized Relator for his plan to use the DCM's assistance. Mr. Ware insisted that Relator needed to be solely responsible for conducting the iPro clinic to maximize the sales opportunities. Mr. Ware refused to allow the DCM to perform the procedure and instead required Relator to perform the invasive medical procedures. Relator complied,

fearing that his job was on the line if he refused to do so. However, Relator was very uncomfortable with performing the medical procedure, especially given that he had to insert the sensor into the upper pubic area of an obese female patient. Prior to this occasion, Relator had never performed insertions on a patient.

574. Relator also held an iPro clinic at Providence Diabetes Center on October 26, 2010 that Mr. Ware attended. Because the Providence Diabetes Center did not permit Medtronic to perform the medical procedure, Mr. Ware could not force Relator to do so. Despite not conducting the iPro clinics himself, Relator successfully convinced three patients to seek pump therapy for a total of ten new patients requesting pump therapy in a two day period.

575. Mr. Ware harshly criticized Relator during the second field ride for being unwilling to examine patient databases both at Providence Hospital and in the office of Dr. John Gallen for the purpose of identifying patients who would be potential customers for pump therapy. Relator objected that reviewing the patient databases would be a HIPAA violation. Mr. Ware nevertheless responded that Relator was required to review the patient databases as directed even though Teri Martisek, the RN responsible for Providence Hospital's database, and Dr. Gallen also objected to providing Relator with access to the databases.

576. Subsequent to the second field ride, Relator continued to talk to coworkers about his opposition to Medtronic's requirement that he personally perform the iPro clinic procedure without the assistance of medical personnel. Relator learned from his DCM that another Medtronic employee had informed Mr. Ware about Relator's continued practice of utilizing the DCM to insert needles and otherwise perform the

medical aspects of the iPro clinics rather than performing the medical procedures himself. Relator began to feel the adverse effects of his refusal to violate the law. Other team members began to marginalize him and stopped returning his calls and emails.

577. By email dated November 1, 2010, Mr. Ware acknowledged that Relator's performance in October 2010 was strong. He stated: "Strong close to the month! Great job."

578. Notwithstanding Relator's strong performance, Mr. Ware remained upset that Relator had involved his DCM in performing procedures at the iPro clinics and had refused to access the hospital's patient database, in clear violation of HIPAA. On November 2, 2010, Mr. Ware wrote Relator a Letter of Concern admonishing him for involving the DCM in iPro clinics. Mr. Ware reiterated that it is the responsibility of the Territory Managers "to perform and complete iPro clinics on their own." Mr. Ware also criticized Relator for his unwillingness to press Ms. Martisek at Providence Hospital for access to the hospital's patient database which he had told Mr. Ware would be a HIPAA violation. Mr. Ware issued the Letter of Concern notwithstanding Relator's objectively satisfactory performance, including that Relator continued to be a sales leader in the district and region.

579. Concerned with the impropriety of Mr. Ware's instructions, Relator contacted the FDA during November 2010 and reported his concerns regarding the manner in which Medtronic conducted iPro clinics. Relator also reported his broader concerns about Medtronic's improper sales and marketing practices, including its off label promotion of its pump and CGM sensor device; its payments and services to

physicians as quid pro quo for assistance by physicians in marketing its products in relation to the iPro clinics; and its related fraudulent practices. The FDA advised Relator that his concern about being required to perform the iPro clinics himself was outside the FDA's jurisdiction, but within that of the Oregon Medical Board.

580. On December 5, 2010, Relator filed complaint number 118060 with the FDA which included substantially all of the practices referenced herein. Relator had repeatedly raised his concerns regarding the off-label practices he reported in this Complaint and detailed to coworkers in the past.

581. On January 7, 2011, Mr. Ware placed Relator on a Corrective Action Plan, in further retaliation for Relator's objections: to being required to perform the iPro clinics without participation of qualified medical personnel; to the manner in which Medtronic was providing free services to physicians in connection with the iPro clinics; and to Mr. Ware's direction that he electronically search doctors' patient databases for patients who are on MDI therapy. The Corrective Action Plan required Relator "to set up and conduct" a minimum of five iPro clinics per week upon threat of imposition of a Performance Improvement Plan and possible termination of employment.

582. On or around January 13, 2011, Relator contacted the Oregon Medical Board to report his concerns about Mr. Ware's direction that he perform medical procedures while conducting iPro clinics. Staff at the Oregon Medical Board advised Relator that the iPro procedure, involving insertion of a medical device under a patient's skin, is a medical diagnostic procedure which may only be lawfully performed by licensed medical personnel consistent with Oregon law.

583. On January 24, 2011, Relator spoke to Alicia Markety, a MiniMed Human

Resources representative based in California, about the Corrective Action Plan Mr. Ware had placed him on. Ms. Markety explained that a Corrective Action Plan is typically the first step in the performance management process. She further explained that after being placed on a Corrective Action plan, an employee is typically placed on a Performance Improvement Plan, and that at the end of the Performance Improvement Plan, if the sales goals or the expectations are not met, the employee would face termination.

584. By email of January 31, 2011, Relator informed Mr. Ware that he intended to report “all of the issues you have brought to the table with the proper internal Medtronic Corporate departments.” He further stated "it is likely and should be expected that not only will there be very few calls this week and that it is possible that entire days will be spent in conversation with Medtronic Corporate. If you have an issue with this please let me know right now so that I can address them with the respective divisions of Medtronic Corporate as I discuss my performance as well as your conduct and actions with them at length." Relator further stated, "I will expect to not receive any retaliatory emails for not having enough calls to hit the criteria for the CAP you created."

585. By email dated February 1, 2011, to Celeste Ortiz, Defendant MiniMed’s Vice President of Human Resources based in California, Relator alerted Medtronic to the fact that Mr. Ware was trying to “apply pressure on [him] and push[ing him] out of the company.” He provided a detailed refutation to the statements Mr. Ware made in Relator's Corrective Action Plan, including comprehensive data demonstrating that he was outperforming other Territory Managers in his District, none of whom were put on a Corrective Action Plan. Ms. Ortiz responded by email that evening advising Relator that

she was in receipt of his email and wanted an opportunity to review the matter. She further advised Relator that she would be in touch with him later that week to follow up. By email on February 4, 2011, Ms. Ortiz informed Relator that they had "looked into" the matters he raised, but were continuing his Corrective Action Plan.

586. On February 8, 2011, the FDA visited Medtronic MiniMed corporate headquarters in Northridge, California, commencing an investigation of the practices reported by Relator through his complaint of December 5, 2010. Given Relator's vocal opposition to Medtronic's practices, which was well-known to Relator's superiors and co-workers alike, Medtronic correctly concluded that the FDA's initiation of an investigation into off-label promotion and kickbacks was precipitated by the information Relator had provided. Indeed, Relator's coworkers openly speculated that he was the source of the FDA complaint. Moreover, Medtronic had access to the records of Relator's use of his company cell phone which he used in his early efforts to make contact with the FDA in November 2010.

587. The same day that the FDA visited MiniMed and initiated its investigation into company practices, Ms. Ortiz directed Relator to work with Medtronic's legal department to address any concerns he had. Following her direction, on February 8, 2011 Relator emailed Reuben Mjaanes, Principal Legal Counsel for Medtronic, the Legal Department contact Ms. Ortiz had provided him, who is based in Minnesota.

588. On February 9, 2011, Relator sent a memorandum to Mr. Mjaanes, in which he reported that Mr. Ware had insisted at the time of his first field ride that he personally perform the iPro clinics notwithstanding that he told Mr. Ware at that time that the procedure "was not lawfully performed by a Territory Manager." He further

stated his belief that the practice posed a substantial danger to public health and safety. Relator further reported that he told Mr. Ware at the same time that doing the clinics for the physicians "and then telling them that they can bill and make so much money was not right" and "sounded like a kickback to me." He reported that Mr. Ware responded that he "needed to use the economic model to sell them on the finances of the ipro" and that he (Relator) "needed to take over so that we could convert all of their MDI patients to pump therapy."

589. Relator further reported through the February 9, 2011 memorandum to Medtronic's Principal Legal Counsel that "[s]ince pushing back to Mike Ware during our first field ride" he had "been harassed and retaliated against" including most recently through imposition of the Corrective Action Plan. Mr. Mjaanes did not interview Relator about his allegations.

590. Instead, by email dated February 17, 2011, Mr. Mjaanes informed Relator that he and Medtronic's Compliance had reviewed the "iPro issues [he] raised" and that "[i]n neither case, was there a finding that [he was] being retaliated against or that performance issues were not being addressed appropriately." Upon information and belief, Medtronic failed to conduct an appropriate investigation into the matters Relator had reported.

591. On February 28, 2011, just twenty days after the FDA's visit to Medtronic Diabetes corporate headquarters and nineteen days after Relator contacted Medtronic's legal department, Mr. Ware and a MiniMed Human Resources representative in California telephoned Relator and informed him that he was fired. Mr. Ware stated that the reason for the termination was that Relator had not met all the provisions of the

Corrective Action Plan to his complete satisfaction. Mr. Ware then noted that "more importantly," Relator's "behavior" is what led to his termination. Relator pressed for the reasons for such a decision, pointing out that his sales were better than prevailing levels for the nation as a whole. Mr. Ware responded that “we made a business decision to terminate your employment effective immediately based on your current performance as well as and more importantly your behaviors to this point through the Corrective Action Plan.” These explanations were pretextual. Aside from Relator’s objections to practices that he reasonably believed violated federal and state law, including particularly those associated with conduct of the iPro clinics, Relator had not been criticized or counseled about any alleged "behavior" problems. Medtronic MiniMed officials in California participated in the decision to terminate Relator’s employment and actually approved his termination.

592. Mr. Ware’s treatment of Relator constituted disparate treatment. Relator's performance was objectively better than Territory Managers who were not placed on a Corrective Action Plan or terminated. Mr. Ware's treatment of Relator stood in stark contrast to his treatment of Mark Collingwood, another Territory Manager in the same district. Despite achieving similar sales numbers throughout the time period in question, Mr. Ware placed Relator on a Corrective Action Plan on January 7, 2011, but did not place Mr. Collingwood on such a plan. On February 8, 2011, after Relator had repeatedly complained that Mr. Ware had singled him out compared to similar performers, Mr. Ware also placed Mr. Collingwood on a Corrective Action Plan that was virtually identical to that of Relator’s. Mr. Ware’s treatment of Mr. Collingwood while he was on the plan, however, was starkly different than his treatment of Relator. Both Mr.

Collingwood and Relator performed strongly while on their Corrective Action Plans, but neither was able to meet the unrealistic goals Mr. Ware had set for them in the plan. At the conclusion of Relator's plan, Medtronic terminated Relator without first placing him on a Performance Improvement Plan as was the company's standard practice. When Mr. Collingwood reached the conclusion of his Corrective Action Plan, Mr. Ware congratulated him and told him that the Corrective Action Plan was not a disciplinary action, but rather a "management tool."

593. Almost immediately after terminating Relator's employment, Mr. Ware told Relator's former co-worker that Relator was suing Medtronic and directed the co-worker to have no contact with Relator. This statement indicates that Medtronic was aware that Relator was the source of the FDA investigation, since Medtronic could not have known about this suit until it was unsealed on August 21, 2012.

594. Defendants' conduct has caused continuing damage to Relator's reputation and career.

CLAIMS ON BEHALF OF THE UNITED STATES

Count I
Federal False Claims Act
31 U.S.C. §§ 3729(a)(1)(A), B), and (G)

595. The allegations in the foregoing paragraphs are re-alleged as if fully set forth herein.

596. The False Claims Act, 31 U.S.C. § 3729(a)(1)(A), (B), and (G) imposes liability upon, inter alia, those who knowingly present or cause to be presented false claims for payment or approval, and those who make or use, or cause to be made or used, false records or statements material to a false claim or to an obligation to pay

money to the government, or those who knowingly conceal, improperly avoid or decrease an obligation to pay money to the government.

597. Defendants knowingly and willfully violated the AKS and Stark Statute by offering and paying illegal remuneration to government healthcare program providers in exchange for the ordering of their medical devices and supplies. Defendants knew these violations resulted in claims submitted to government healthcare programs. As a result, Defendants knowingly made and caused to be made material misrepresentations to government healthcare programs regarding the compliance of those claims with the AKS and Stark Statute.

598. Defendants also knowingly engaged in misleading and/or false promotional schemes to induce government healthcare programs providers to order medical devices, supplies and drugs for unlabeled and noncovered and payable uses which were not reasonable and necessary. Defendants knew that these schemes resulted in claims submitted to government healthcare programs.

599. Defendants knowingly engaged in a scheme to make and cause to be made material misrepresentations to providers and government healthcare programs regarding the eligibility of claims for payment under government healthcare conditions for coverage of the pump for Type 2 patients. Defendants knew that these schemes resulted in claims submitted to government healthcare programs.

600. Defendants' actions, if known, would have affected the United States and the States' decision to pay the resulting claims.

601. Defendants' actions violated material conditions of payment under government healthcare programs.

602. The resulting claims are false claims.

603. Defendants acted knowingly, as that term is used in the False Claims Act.

604. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to government healthcare programs for payment or approval, within the meaning of 31 U.S.C. § 3729(a)(1)(A).

605. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, material to a false or fraudulent claim to government healthcare programs, within the meaning of 31 U.S.C. § 3729(a)(1)(B).

606. By virtue of the acts described above, defendants received overpayments from government healthcare programs for orders for medical devices and supplies resulting from its illegal inducements and material misrepresentations to government healthcare providers. Defendants failed to return the money to the Government in a timely manner. Defendants' ongoing and knowing failure to report these overpayments violates the False Claims Act, 31 U.S.C. § 3729(a)(1)(G).

607. The United States, unaware of the falsity of the records, statements and claims made or caused to be made by the defendants, paid and continues to pay the claims that would not be paid but for defendants' unlawful conduct.

608. Because the United States would not have paid for services which it knew to have been the result of illegal inducements and material misrepresentations to the ordering providers, the United States has been harmed in an amount equal to the value paid by the United States.

609. By reason of the defendants' acts, the United States has been damaged,

and continues to be damaged, in substantial amount to be determined at trial.

CLAIMS ON BEHALF OF THE STATES

Count II
Violations of State False Claims Acts

610. The allegations in the foregoing paragraphs are re-alleged as if fully set forth herein.

611. Relator asserts claims for treble damages and penalties under the False Claims Acts of California, Colorado, Connecticut, Delaware, the District of Columbia, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, and Wisconsin ("Plaintiff States").

612. The False Claims Acts of the Plaintiff States impose liability upon, inter alia, those who knowingly present or cause to be presented false claims for payment or approval, and those who make or use, or cause to be made or used, false records or statements material to a false claim. In order to preserve brevity in this Amendment, citations to the False Claims Acts of the Plaintiff States are provided in Appendix B (the language of each state statute were provided in separate counts in the prior amendment, Doc. 38).

613. Compliance with federal and state healthcare laws, including the federal AKS and respective state AKSs, is a material condition of payment of claims submitted to the Medicaid Programs of the Plaintiff States. *See* Appendix B, Column 3 for the compiled citations of the state anti-kickback prohibitions.

614. Defendants knowingly presented or caused false claims to be submitted to

the Medicaid programs of the Plaintiff States by engaging in illegal kickback schemes, in knowing violation of material conditions of payment of those programs.

615. Defendants knowingly presented or caused false claims to be submitted to the Medicaid programs of the Plaintiff States by knowingly engaging in misleading and/or false promotional schemes to induce the government healthcare providers to order medical devices, supplies and drugs for unlabeled and noncovered and payable uses that were not reasonable and necessary.

616. Defendants knowingly presented or caused false claims to be submitted to the Medicaid Programs of the Plaintiff States by knowingly engaging in a scheme to make and cause to be made material misrepresentations to providers and government healthcare programs regarding the eligibility of claims for payment under government healthcare conditions for coverage of the pump for Type 2 patients.

617. Defendants' actions, if known, would have affected the Plaintiff State Governments' decisions to pay the resulting claims.

618. Defendants' actions violated material conditions of payment under the Plaintiff States' healthcare programs.

619. The resulting claims are noncovered and nonpayable and are false claims.

620. By virtue of the acts described above, defendants knowingly presented or caused to be presented, false or fraudulent claims to the Plaintiff State Governments for payment or approval.

621. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Plaintiff State Governments to approve and pay such false and fraudulent

claims.

622. By virtue of the acts described above, defendants knowingly and improperly avoided or decreased an obligation to transmit money or property to the Plaintiff State Governments. Defendants received overpayments from government healthcare programs for orders for medical devices and supplies resulting from its illegal inducements and material misrepresentations to government healthcare providers. Defendants failed to return the money to the Plaintiff State Governments in a timely manner.

623. Defendants acted knowingly, as that term is used in the False Claims Acts of the named States.

624. The Plaintiff State Governments, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for Defendants' unlawful conduct.

625. By reason of the Defendants' acts, the Plaintiff States have been damaged, and continue to be damaged, in substantial amount to be determined at trial.

Count III
Violations of California & Illinois Insurance Frauds Prevention Acts
Cal. Ins. Code § 1871.7; 740 Ill. Comp. Stat. §92

626. The allegations in the foregoing paragraphs are re-alleged as if fully set forth herein.

627. Relator alleges claims for treble damages and penalties under the California Insurance Frauds Prevention Act, Cal. Ins. Code § 1871.7, as amended, and the Illinois Insurance Claims Fraud Prevention Act, 740 Ill. Comp. Stat. § 92 (referred to

in this Count as "the Acts"). The Acts provide for qui tam civil actions to create incentives for private individuals to prosecute violations of the statute. Cal. Ins. Code §1871.7; 740 Ill. Comp. Stat. §92/15(a). The Acts provide for civil recoveries against persons who violate the provisions of the Act or the provisions of each State's Penal Code (noted below), including recovery of up to three times the amount of any fraudulent insurance claims, and fines of between $5,000 and $10,000 for each such claim. Cal. Ins. Code §1871.7(b); 740 Ill. Comp. Stat. § 92/5(b).

628. Section 550 of the California Penal Code prohibits, among other things,

- knowingly mak[ing] or caus[ing] to be made any false or fraudulent claim for payment of a health care benefit;
- present[ing] or caus[ing] to be presented any written or oral statement as part of, or in support of or opposition to, a claim for payment or other benefit pursuant to an insurance policy, knowing that the statement contains any false or misleading information concerning any material fact.
- Conceal[ing], or knowingly fail[ing] to disclose the occurrence of, an event that affects any person's initial or continued right or entitlement to any insurance benefit or payment, or the amount of any benefit or payment to which the person is entitled.

Cal. Penal Code § 550.

629. Article 46 of the Illinois Criminal Code provides criminal penalties for any person who commits the offense of insurance fraud, which includes "the making of a false claim or by causing a false claim to be made on any policy of insurance issued by an insurance company…" 720 Ill. Comp. Stat. §5/46-1(a).

630. By virtue of the acts described in this Complaint, defendants knowingly presented or caused to be presented false or fraudulent claims for health care benefits, in violation of California Penal Code §550(a) and the Illinois Criminal Code Article 46.

631. Each claim for reimbursement that was a result of defendants' illegal practices represents a false or fraudulent record or statement, and a false or fraudulent claim for payment.

632. Private insurers, unaware of the falsity of the records, statements and claims made or caused to be made by defendants, paid and continue to pay the claims that would not be paid but for defendants' unlawful conduct.

633. The California and Illiniois State Governments are entitled to receive three times the amount of each claim for compensation for false claims submitted in violation of Cal. Ins. Code §1871.7 and 740 Ill. Comp. Stat. § 92. Additionally, the California and Illinois State Governments are entitled to the maximum penalty of $10,000 for each and every violation alleged herein.

CLAIMS ON BEHALF OF RELATOR ADAM WITKIN PERSONALLY

Count IV
Federal False Claims Act
31 U.S.C. § 3730(h)

634. The allegations in the foregoing paragraphs are re-alleged as if fully set forth herein.

635. The False Claims Act, 31 U.S.C. § 3730(h), provides for relief from Defendants' retaliatory actions as necessary to make Relator whole for being subjected to unlawful discharge from employment and otherwise subjected to unlawful discrimination and retaliation as a consequence of lawful acts done by him to report what he reasonably believed were false claims for payment from federal payors resulting from Defendants' marketing practices and in furtherance of a possible action

for violation of the federal False Claims Act.

636. As alleged above, Relator engaged in lawful acts in furtherance of efforts to stop one or more violations of 31 U.S.C. § 3729.

637. Defendants were on notice of Relator's objections to corporate practices, including improper sales and marketing practices, which were in violation of material conditions of payment governing government healthcare claims.

638. Because of Relator's lawful acts (a-d) above, Relator was subjected to retaliatory discrimination in the terms and conditions of his employment, including his wrongful termination on February 28, 2011. Defendants' actions constituted retaliation for Relator's lawful acts in reporting, attempting to stop, and acting in furtherance of other efforts to stop what he reasonably believed were actions by Medtronic in violation of the FCA and federal Anti-Kickback statute and in furtherance of a possible qui tam action.

639. As a direct and proximate result of the foregoing, Relator has lost the benefits and privileges of employment, and has suffered continuing damage to his reputation and career. Relator is entitled to all relief necessary to make him whole.

Count V
Discrimination for Whistleblowing in Violation of ORS § 659A.199

640. The allegations in the foregoing paragraphs are re-alleged as if fully set forth herein.

641. ORS § 659A.199 makes it "an unlawful employment practice for an employer to discharge, or in any manner discriminate or retaliate against an employee for the reason that the employee has in good faith reported information that the employee believes is evidence of a violation of a state or federal law, rule or regulation."

The provision states further that the remedies thereby provided are in addition to any common law or other remedy that may be available. ORS § 659A.885 authorizes a civil action for violation of designated provisions including § 659A.199.

642. Through his verbal objections to Mike Ware on September 28 and 29, 2010 and thereafter, his submission of a complaint to the FDA on December 5, 2010, his email dated January 31, 2011 to Mike Ware, and his memorandum sent February 9, 2011 to Medtronic's corporate legal department, Relator reported what he reasonably and in good faith believed amounted to violations of the federal Food Drug & Cosmetic Act, the federal Anti-Kickback Statute, the federal False Claims Act and the law of Oregon prohibiting performance of medical diagnostic procedures by unlicensed personnel.

643. Medtronic discriminated and retaliated against Relator in violation of ORS § 659A.199 when it: issued to Relator the Letter of Concern, placed Relator on a Corrective Action Plan; subjected Relator to other discrimination and retaliation, and terminated his employment.

644. As a direct and proximate result of the foregoing, Relator has lost the benefits and privileges of employment, and has suffered continuing damage to his reputation and career. Relator is entitled to all relief necessary to make him whole.

645. Defendants engaged in conduct described above in deliberate disregard of the rights of others, which constitutes wanton misconduct.

COUNT VI
Wrongful Termination in Violation of
Common Laws of Oregon and California

646. The allegations in the foregoing paragraphs are re-alleged as if fully set

forth herein.

647. Relator alleged claims for relief from wrongful termination in violation of fundamental public policy pursuant to the common laws of Oregon and California. The common laws of Oregon and California prohibit an employer in those States from discharging an individual from at-will employment for reporting what the employee reasonably believes to be a violation of a statute, law or regulation where the employee makes the report pursuant to an important public duty or for refusing to perform what the employee reasonably believes to be an unlawful act.

648. Through the filing of complaint no. 118060 with the United States Food and Drug Administration on December 5, 2011; his oral objections to Mike Ware of September 28 and 29, 2010 and thereafter; his email to Mr. Ware dated January 31, 2011 indicating his intention to bring the iPro clinic issues to the attention of the proper departments of Medtronic and his memorandum sent February 9, 2011 to Medtronic's corporate legal department, Relator reported what he reasonably believed to be violations of federal law and the laws of Oregon and California that implicate fundamental public policy including:

a. Medtronic's unlawful off-label marketing practices in violation of the federal Food Drug & Cosmetic Act as set forth *supra* and reported through Relator's complaint no. 118060 to the Food and Drug Administration;

b. Medtronic's unlawful practices in violation of the federal health care Anti-Kickback statute as set forth *supra* and reported through Relator's complaint no. 118060 to the Food and Drug Administration;

c. Medtronic's practices regarding the conduct of iPro clinics as reported in Relator's memorandum sent February 9, 2011 to Medtronic's corporate legal department in violation of California's Unfair Competition Law, Cal. Bus & Prof. Code §§ 17200 *et seq.*;

d. Medtronic's requirement that he and other sales personnel, not licensed pursuant to Oregon law, nevertheless perform medical diagnostic procedures constituting the practice of medicine in connection with the conduct of iPro Clinics without being licensed as required by ORS §§ 677.085, .495, .520;

e. Medtronic's unlawful practices in violation of the California False Claims Act and California Insurance Frauds Prevention Act as set forth *supra* and reported through Relator's complaint no. 118060 to the Food and Drug Administration.

649. In making the foregoing reports, Relator acted pursuant to important public duties to prevent and remedy fraud on Medicare and other government health care payors and to protect public health and safety by calling attention to and seeking to prevent the unauthorized practice of medicine.

650. Medtronic's action in discharging Relator was in retaliation for reports made in fulfillment of public duties and for his refusal to engage in what he reasonably believed would be acts violating the federal Food Drug & Cosmetic Act, the federal Anti-Kickback Statute, the federal False Claims Act and the law of Oregon prohibiting performance of medical diagnostic procedures by unlicensed personnel.

651. As a direct and proximate result of the foregoing, Relator has lost the benefits and privileges of employment, and has suffered continuing damage to his reputation and career. Relator is entitled to all relief necessary to make him whole.

652. Defendants engaged in conduct described above in deliberate disregard of the rights of others, which constitutes wanton misconduct.

653. Defendants engaged in the conduct described above with malice – meaning that Defendants' conduct was meant to cause injury to Relator or was despicable conduct which was carried on by the Defendants with a willful and conscious

disregard of the rights or safety of others, or with oppression, or fraud.

PRAYER

WHEREFORE, Relator prays for judgment against the defendants as follows:

A. that Defendants cease and desist from violating 31 U.S.C. § 3729 *et seq.*, and the counterpart provisions of the state statutes set forth above;

B. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the United States has sustained because of defendants' actions, plus a civil penalty of not less than $5,000 and not more than $11,000 for each violation of 31 U.S.C. § 3729;

C. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the Plaintiff States have sustained because of defendants' actions, plus the maximum civil penalty allowed for each violation of the state False Claims Acts;

D. that this Court enter judgment against Defendants in an amount equal to three times the amount of each claim for compensation submitted by defendant in violation of Cal. Ins. Code §1871.7(b) and 740 Ill. Comp. Stat. § 92, plus a civil penalty of $10,000 for each violation of those provisions;

E. that Relator be awarded the maximum amount allowed pursuant to § 3730(d) of the False Claims Act, and the equivalent provisions of the state statutes set forth above;

F. that the Court enter judgment against the Defendants for the States', Commonwealths' and District's costs of this action;

G. that this Court enter judgment against Defendants pursuant to 31 U.S.C. §

3730(h) including an order reinstating Relator to his employment with the full seniority and benefits he would have had but for his retaliatory discharge and awarding him two times the amount of his back pay and compensation for special damages including litigation costs and reasonable attorney's fees;

H. that this Court enter judgment against Defendants for wrongful termination in violation of the ORS § 659A.199, for unlawful discrimination and retaliation and order injunctive relief including but not limited to Relator's reinstatement with back pay, and additionally award compensatory and punitive damages, and attorney's fees and legal expenses;

I. That this Court enter judgment against Defendants for wrongful termination in violation of the common laws of Oregon and California with awards of compensatory and punitive damages;

J. that Relator be awarded all costs of this action, including attorneys' fees and expenses;

K. that the United States Government, the respective States and Relator receive all relief, both at law and in equity, to which they may reasonably appear entitled.

L. that Relator recover such other relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Relator hereby demands a trial by jury.

Dated: July 31, 2013

Respectfully submitted,

/s/ Jennifer M. Verkamp
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CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing was sent via the Court's electronic filing system, and served to all counsel of record on July 31, 2013.

/s/ Jennifer M. Verkamp
Jennifer M. Verkamp

APPENDIX A								
Doctor/Provider	**Practice**	**Location**	**Prohibited Financial Relationship** (*key provided below)	**Patient**	**Insurance**	**Date of Service, Order, or Confirmation of Shipment**	**Resulting Claims Submitted**	**Pump Model/Serial Number**
Bailey, George	Providence Medical Group	Providence, OR	Above-fair market value training payments (RN CDE Teri Martisak).	S.M.	Medicaid	2/25/2011	Pump, Insulin	Model: 523
Bassett, Martin L.	Willamette Valley Endocrinology	Salem, OR	Nurse-in-the-Office (later benefited from Free iPro clinic management and CTD).	K.C.	Medicare/ Medicaid	4/16/2009	Pump, Insulin	Model: 722 SN: PAR381676U
Bassett, Martin L.	Willamette Valley Endocrinology	Salem, OR	Nurse-in-the-Office (later benefited from Free iPro clinic management and CTD).	J.M.	Medicare	6/30/2009	Pump, Insulin	not available
Bradley, Mark	VA, Roseburg	Roseburg, OR	Nurse-in-the-Office.	G.F.	Medicare	5/16/2007	Pump, Insulin	not available
Britsch, Barbara (PA)	Firehouse Diabetes Center	Salem, OR	Above-fair market value training payments (Lindita Nako).	I.B.	Medicare	5/9/2008	Pump, Insulin	not available
Britsch, Barbara (PA)	Firehouse Diabetes Center	Salem, OR	Above-fair market value training payments (Lindita Nako).	B.G.	Medicare	3/23/2004	Pump, Insulin	not available
Britsch, Barbara (PA)	Firehouse Diabetes Center	Salem, OR	Above-fair market value training payments (Lindita Nako).	L.P.	Medicare	1/2/2008	Pump, Insulin	not available
Britsch, Barbara (PA)	Firehouse Diabetes Center	Salem, OR	Above-fair market value training payments (Lindita Nako).	S.S.	Medicare	1/14/2009	Pump, Insulin	not available
Britsch, Barbara (PA)	Firehouse Diabetes Center	Salem, OR	Above-fair market value training payments (Lindita Nako).	J.R.	Medicare	4/25/2006	Pump, Insulin	Model: 508 SN: B7909-AOEC
Carroll, Mary	Bend Memorial Clinic	Bend, OR	Above-fair market value training payments (NPs Jennifer McDonough followed by Tonya Koopman). Free lunches; Tonya Koopman received a paid trip to Las Vegas in 2010 for a CTD symposium.	C.K.	Medicare	6/20/2006	Pump, Insulin	SN: PAR122751UDB35
Carroll, Mary	Bend Memorial Clinic	Bend, OR	Above-fair market value training payments (NPs Jennifer McDonough followed by Tonya Koopman). Free lunches; Tonya Koopman received a paid trip to Las Vegas in 2010 for a CTD symposium.	D.B.	Medicare	7/10/2006	Pump, Insulin	Model: MMT-522NAL
Carroll, Mary	Bend Memorial Clinic	Bend, OR	Above-fair market value training payments (NPs Jennifer McDonough followed by Tonya Koopman). Free lunches; Tonya Koopman received a paid trip to Las Vegas in 2010 for a CTD symposium.	D.F.	Medicare	11/23/2005	Pump, Insulin	Model: Paradigm 712 SN: 104034
Carroll, Mary	Bend Memorial Clinic	Bend, OR	Above-fair market value training payments (NPs Jennifer McDonough followed by Tonya Koopman). Free lunches; Tonya Koopman received a paid trip to Las Vegas in 2010 for a CTD symposium.	E.J.	Medicare	November, 2010	Pump, Insulin	Model: 523R SN: PAR451799U
Carroll, Mary	Bend Memorial Clinic	Bend, OR	Above-fair market value training payments (NPs Jennifer McDonough followed by Tonya Koopman). Free lunches; Tonya Koopman received a paid trip to Las Vegas in 2010 for a CTD symposium.	J.L.	Medicare	11/11/2008	Pump, Insulin	not available

Carroll, Mary	Bend Memorial Clinic	Bend, OR	Above-fair market value training payments (NPs Jennifer McDonough followed by Tonya Koopman). Free lunches; Tonya Koopman received a paid trip to Las Vegas in 2010 for a CTD symposium.	J.V.	Medicare	3/29/2006	Pump, Insulin	Model: MMT-512RNAL SN: SVA213880A
Carroll, Mary	Bend Memorial Clinic	Bend, OR	Above-fair market value training payments (NPs Jennifer McDonough followed by Tonya Koopman). Free lunches; Tonya Koopman received a paid trip to Las Vegas in 2010 for a CTD symposium.	K.L.	Medicare	6/2/2009	Pump, Insulin	not available
Carroll, Mary	Bend Memorial Clinic	Bend, OR	Above-fair market value training payments (NPs Jennifer McDonough followed by Tonya Koopman). Free lunches; Tonya Koopman received a paid trip to Las Vegas in 2010 for a CTD symposium.	R.J.	Clear Choice Medicare Advantage	10/20/2009	Pump, Insulin	Pump: 522
Carroll, Mary	Bend Memorial Clinic	Bend, OR	Above-fair market value training payments (NPs Jennifer McDonough followed by Tonya Koopman). Free lunches; Tonya Koopman received a paid trip to Las Vegas in 2010 for a CTD symposium.	W.E.	Medicare	6/29/2009	Pump, Insulin	not available
Chamberlain, Thomas	Physicians Building Group	Salem, OR	Nurse-in-the-Office.	J.C.	Medicare	6/10/2009	Pump, Insulin	not available
Chamberlain, Thomas	Physicians Building Group	Salem, OR	Nurse-in-the-Office.	D.P.	Medicare	1/18/2008	Pump, Insulin	Pump: 508
Chamberlain, Thomas	Physicians Building Group	Salem, OR	Nurse-in-the-Office.	M.R.	Medicare	8/12/2009	Pump, Insulin	not available
Chamberlain, Thomas	Physicians Building Group	Salem, OR	Nurse-in-the-Office.	P.S.	Medicare	5/27/2009	Pump, Insulin	not available
Chamberlain, Thomas	Physicians Building Group	Salem, OR	Nurse-in-the-Office.	N.C.	Medicare	5/29/2009	Pump, Insulin	not available
Chamberlain, Thomas	Physicians Building Group	Salem, OR	Nurse-in-the-Office.	L.L.	Medicare	10/22/2007	Pump, Insulin	not available
Chamberlain, Thomas	Physicians Building Group	Salem, OR	Nurse-in-the-Office.	A.L.	Medicare	2/23/2007	Pump, Insulin	not available
Cirullo, Ronald	Independent and then Oregon Medical Group	Eugene, OR	Nurse-in-the-Office.	H.S.	Medicare	3/18/2009	Pump, Insulin	not available
Cirullo, Ronald	Independent and then Oregon Medical Group	Eugene, OR	Nurse-in-the-Office.	F.S.	Medicare	3/29/2005	Pump, Insulin	not available
Cirullo, Ronald	Independent and then Oregon Medical Group	Eugene, OR	Nurse-in-the-Office.	L.S.	Medicare	2/3/2009	Pump, Insulin	not available
Cirullo, Ronald	Independent and then Oregon Medical Group	Eugene, OR	Nurse-in-the-Office.	J.W.	Medicare	9/15/2008	Pump, Insulin	not available
Cirullo, Ronald	Independent and then Oregon Medical Group	Eugene, OR	Nurse-in-the-Office.	S.G.	CHAMPVA	1/14/2008	Pump, Insulin	not available
Cirullo, Ronald	Independent and then Oregon Medical Group	Eugene, OR	Nurse-in-the-Office.	F.W.	Medicare	2/25/2011	Upgrade Pump, Insulin	Model: 723 SN: PAR489132U
Duren, Christian (PA)	Dr. James W Theen's office	Medford, OR	Above-fair market value training payments (Gina Jones); Nurse-in-the-Office (later benefited from Free iPro clinic management).	V.M.	Medicare	11/28/2007	Pump, Insulin	not available

Eccles, Ralph	Cascade East Rural Family Medicine	Klamath Falls, OR	Nurse-in-the-Office; Free iPro clinic management.	I.H.	Medicare	8/21/2008	Pump, Insulin	not available
Eddy, Richard	Institute of Diabetes and Endocrinology	Medford, OR	Above-fair market value training payments (RN CDE Sue Amidon).	M.R.	Medicare	11/5/2009	Pump, Insulin	Model: 522R SN: PAR331508U
Eddy, Richard	Institute of Diabetes and Endocrinology	Medford, OR	Above-fair market value training payments (RN CDE Sue Amidon).	J.T.	Medicare	5/17/2006	Pump, Insulin	Model: 712R
Farmer, Jane	Peace Health Diabetes and Endocrinology	Eugene, OR	Free iPro clinic management; Nurse-in-the-Office.	H.M.	LIPA-Medicaid	November, 2010	Pump, Insulin	SN: PAR857744H
Farmer, Jane	Peace Health Diabetes and Endocrinology	Eugene, OR	Nurse-in-the-Office (also later benefited from Free iPro clinic management).	J.M.	Medicaid	7/16/2009	Pump, Insulin	not available
Gallant, James D	Corvallis Internal Medicine		Free iPro clinic management; Free lunches.	C.W.	Medicare	5/11/2009	Pump, Insulin	not available
Gallant, James D	Corvallis Internal Medicine		Free iPro clinic management; Free lunches.	D.V.	Medicare	4/28/2009	Pump, Insulin	not available
Gallen, John	Medford Diabetes, Endocrinology and Metabolism (2004-2006); Medford Medical Clinic (2006-present)	Medford, OR	Above-fair market value training payments (RN CDE Teri Martisak followed by RN CDE Marianne Neito) (later benefited from Free iPro clinic management).	N.C.	Medicare	5/29/2009	Pump, Insulin	not available
Gallen, John	Medford Diabetes, Endocrinology and Metabolism (2004-2006); Medford Medical Clinic (2006-present)	Medford, OR	Above-fair market value training payments (RN CDE Teri Martisak followed by RN CDE Marianne Neito) (later benefited from Free iPro clinic management).	W.G.	Medicare	8/14/2008	Pump, Insulin	not available
Gallen, John	Medford Diabetes, Endocrinology and Metabolism (2004-2006); Medford Medical Clinic (2006-present)	Medford, OR	Above-fair market value training payments (RN CDE Teri Martisak followed by RN CDE Marianne Neito) (later benefited from Free iPro clinic management).	F.K.	Medicare	8/11/2009	Pump, Insulin	not available
Gallen, John	Medford Diabetes, Endocrinology and Metabolism (2004-2006); Medford Medical Clinic (2006-present)	Medford, OR	Above-fair market value training payments (RN CDE Teri Martisak followed by RN CDE Marianne Neito) (later benefited from Free iPro clinic management).	R.S.	Medicare	3/24/2005	Pump, Insulin	not available
Gallen, John	Medford Diabetes, Endocrinology and Metabolism (2004-2006); Medford Medical Clinic (2006-present)	Medford, OR	Above-fair market value training payments (RN CDE Teri Martisak followed by RN CDE Marianne Neito) (later benefited from Free iPro clinic management).	K.B.	Tricare	4/6/2009	Pump, Insulin	not available
Garrison, Cort	Physicians Building Group	Salem, OR	Nurse-in-the-Office.	M.B.	Medicare	12/19/2008	Pump, Insulin	not available
Garrison, Cort	Physicians Building Group	Salem, OR	Nurse-in-the-Office.	H.S.	Medicare	7/11/2008	Pump, Insulin	not available
Goldstein, Rick	Bend Memorial Clinic	Bend, OR	Above-fair market value training payments (NPs Jennifer McDonough followed by Tonya Koopman). Free lunches; Tonya Koopman received a paid trip to Las Vegas in 2010 for a CTD symposium.	J.N.	Medicare	4/3/2009	Pump, Insulin	not available
Hao, Wei	Alliance Healthcare	Corvallis, OR	Nurse-in-the-Office.	M.C.	Medicare	9/19/2008	Pump, Insulin	not available
Hao, Wei	Alliance Healthcare	Corvallis, OR	Nurse-in-the-Office.	K.F.	Medicare	9/14/2007	Pump, Insulin	not available
Huang, Chuck		Grants Pass, OR	Free iPro clinic management; Nurse-in-the-Office.	J.H.	Medicare	4/21/2009	Pump, Insulin	not available
Huang, Chuck		Grants Pass, OR	Free iPro clinic management; Nurse-in-the-Office.	D.T.	Medicare	8/15/2008	Pump, Insulin	not available

Huang, Chuck		Grants Pass, OR	Free iPro clinic management; Nurse-in-the-Office.	F.V.	Mid Rogue IPA	8/15/2008	Pump, Insulin	not available
Huang, Chuck		Grants Pass, OR	Free iPro clinic management; Nurse-in-the-Office.	G.D.	Medicare	7/28/2008	Pump, Insulin	not available
Jacobson, Kirk	Oak Street Medical	Eugene, OR	Nurse-in-the-Office (later benefited from CTD).	T.W.	Medicaid	8/26/2009	Pump, Insulin	Model: 722
Kelly, Alan	Institute of Diabetes and Endocrinology	Medford, OR	Above-fair market value training payments (RN CDE Sue Amidon). Additional incentives as a paid speaker, paid trip to headquarters, CTD and free supplies.	D.C.	Medicare	11/18/2008	Pump, Insulin	not available
Kelly, Alan	Institute of Diabetes and Endocrinology	Medford, OR	Above-fair market value training payments (RN CDE Sue Amidon). Additional incentives as a paid speaker, paid trip to headquarters, CTD and free supplies.	J.D.	Medicare	11/13/2008	Pump, Insulin	not available
Kelly, Alan	Institute of Diabetes and Endocrinology	Medford, OR	Above-fair market value training payments (RN CDE Sue Amidon). Additional incentives as a paid speaker, paid trip to headquarters, CTD and free supplies.	D.T.	Medicare	4/18/2008	Pump, Insulin	not available
Krishnamurthy, Priya	Physicians Building Group	Salem, Oregon	Free iPro clinic management; Nurse-in-the-Office; lunches and dinners (later benefited from CTD).	J.W.	Medicare	10/25/2010	CPTs for iPro Clinic	N/A
Krishnamurthy, Priya	Physicians Building Group	Salem, Oregon	Free iPro clinic management; Nurse-in-the-Office; lunches and dinners (later benefited from CTD).	J.R.	Medicare	10/25/2010	CPTs for iPro Clinic	N/A
Krishnamurthy, Priya	Physicians Building Group	Salem, Oregon	Free iPro clinic management; Nurse-in-the-Office; lunches and dinners (later benefited from CTD).	J.W.	Medicare	1/24/2011	Pump, u500 insulin	Model: MMT-723NAS SN: PAR887630H
Krishnamurthy, Priya	Physicians Building Group	Salem, Oregon	Free iPro clinic management; Nurse-in-the-Office; lunches and dinners (later benefited from CTD).	C.P.	Medicare	unk.	Pump, Insulin, CPTs for iPro clinic	not available
McCarthy, Patrick	Medford Diabetes, Endcrinology and Metabolism (2004-2006), Advanced Speciality Care/ Endocrinology Services NW LLC (2006-present)	Medford, OR; Bend, OR	Above-fair market value training payments (RN CDE Teri Martisak followed by RN CDE Rita Shearer).	S.C.	Medicare	2/18/2005	Pump, Insulin	not available
McCarthy, Patrick	Medford Diabetes, Endcrinology and Metabolism (2004-2006), Advanced Speciality Care/ Endocrinology Services NW LLC (2006-present)	Medford, OR; Bend, OR	Above-fair market value training payments (RN CDE Teri Martisak followed by RN CDE Rita Shearer).	K.O.	Medicaid	5/10/2004	Pump, Insulin	not available
McCarthy, Patrick	Medford Diabetes, Endcrinology and Metabolism (2004-2006), Advanced Speciality Care (2006-present)	Medford, OR; Bend, OR	Above-fair market value training payments (RN CDE Teri Martisak followed by RN CDE Rita Shearer).	E.Y.	Medicare	11/16/2004	Pump, Insulin	not available
McCarthy, Patrick	Medford Diabetes, Endcrinology and Metabolism (2004-2006), Advanced Speciality Care (2006-present)	Medford, OR; Bend, OR	Above-fair market value training payments (RN CDE Teri Martisak followed by RN CDE Rita Shearer).	M.W.	Medicare	7/7/2009	Pump, Insulin	not available

Mendoza, Noriecel	Ventana Wellness Center	Medford, OR	Above-fair market value training payments (RN CDE Teri Martisak); lunches (Martisak).	D.B.	Medicare	6/12/2008	Pump, Insulin	not available
Mendoza, Noriecel	Ventana Wellness Center	Medford, OR	Above-fair market value training payments (RN CDE Teri Martisak); lunches (Martisak).	S.B.	Medicare	7/21/2009	Pump, Insulin	not available
Mendoza, Noriecel	Ventana Wellness Center	Medford, OR	Above-fair market value training payments (RN CDE Teri Martisak); lunches (Martisak).	T.F.	Medicare	12/17/2008	Pump, Insulin	not available
Mendoza, Noriecel	Ventana Wellness Center	Medford, OR	Above-fair market value training payments (RN CDE Teri Martisak); lunches (Martisak).	D.V.	Medicare	7/8/2008	Pump, Insulin	SN: PAR268743UFAS9
Mendoza, Noriecel	Ventana Wellness Center	Medford, OR	Above-fair market value training payments (RN CDE Teri Martisak); lunches (Martisak).	P.P.	Medicaid	1/11/2008	Pump, Insulin	not available
Michaels, Rodney	Firehouse Diabetes Center	Salem, OR	Above-fair market value training payments (Lindita Nako).	W.D.	Medicare	2/4/2009	Pump, Insulin	not available
Michaels, Rodney	Firehouse Diabetes Center	Salem, OR	Above-fair market value training payments (Lindita Nako).	S.K.	Medicare	3/4/2008	Pump, Insulin	not available
Michaels, Rodney	Firehouse Diabetes Center	Salem, OR	Above-fair market value training payments (Lindita Nako).	M.M.	Medicare	1/24/2008	Pump, Insulin	not available
Michaels, Rodney	Firehouse Diabetes Center	Salem, OR	Above-fair market value training payments (Lindita Nako).	P.R.	Medicare	1/24/2008	Pump, Insulin	not available
Michaels, Rodney	Firehouse Diabetes Center	Salem, OR	Above-fair market value training payments (Lindita Nako).	I.S.	Medicare	1/12/2009	Pump, Insulin	not available
Michaels, Rodney	Firehouse Diabetes Center	Salem, OR	Above-fair market value training payments (Lindita Nako).	S.S.	Medicare	8/3/2005	Pump, Insulin	Model: 723R SN: PAR466898U
Michaels, Rodney	Firehouse Diabetes Center	Salem, OR	Above-fair market value training payments (Lindita Nako).	M.S.	Medicare	1/7/2009	Pump, Insulin	not available
Michaels, Rodney	Firehouse Diabetes Center	Salem, OR	Above-fair market value training payments (Lindita Nako).	C.K.	Medicaid	4/19/2004	Pump, Insulin	not available
Michaels, Rodney	Firehouse Diabetes Center	Salem, OR	Above-fair market value training payments (Lindita Nako)	K.Q.	Medicare	3/30/2005	Pump, Insulin	SN: PAR489100U
Michaels, Rodney	Firehouse Diabetes Center	Salem, OR	Above-fair market value training payments (Lindita Nako).	S.S.	Medicare	November, 2010	Upgrade Pump, Insulin	
Michaels, Rodney	Firehouse Diabetes Center	Salem, OR	Above-fair market value training payments (Lindita Nako).	L.H.	Medicare	November, 2010	Pump, Insulin	SN: PAR421032U
Nelson, John (PA)	Independent and then Oregon Medical Group	Eugene, OR	Nurse-in-the-Office (later benefited from Free iPro clinic management).	L.T.	Tricare	2/4/2009	Pump, Insulin	Pump: 712
Palmer, Derek	St. Charles Health System	Redmond, OR	Above-fair market value training payments (RN CDE Rita Shearer).	J.P.	Medicare	2/25/2011	Pump, Insulin	Model: MMT-715NAS SN: PAR422684U
Pardini, Aaron, M.D.	Peace Health Medical Group	Eugene, OR	Nurse-in-the-Office (later benefited from Free iPro clinic management).	J.D.	Medicare	4/29/2008	Pump, Insulin	not available
Pardini, Aaron, M.D.	Peace Health Medical Group	Eugene, OR	Nurse-in-the-Office (later benefited from Free iPro clinic management).	J.E.	Medicare	1/26/2009	Pump, Insulin	not available

Pardini, Aaron, M.D.	Peace Health Medical Group	Eugene, OR	Nurse-in-the-Office (later benefited from Free iPro clinic management).	T.M.	Medicare	7/1/2009	Pump, Insulin	not available
Pardini, Aaron, M.D.	Peace Health Medical Group	Eugene, OR	Nurse-in-the-Office (later benefited from Free iPro clinic management).	S.S.	Tricare	11/26/2008	Pump, Insulin	not available
Pardini, Aaron, M.D.	Peace Health Medical Group	Eugene, OR	Nurse-in-the-Office (later benefited from Free iPro clinic management).	J.B.	LIPA-Medicaid	10/29/2008	Pump, Insulin	not available
Pardini, Aaron, M.D.	Peace Health Medical Group	Eugene, OR	Nurse-in-the-Office (later benefited from Free iPro clinic management).	D.W.	Oregon Health Plan	5/29/2009	Pump, Insulin	not available
Radhakrishnan, Latha M.D	Physicians Building Group	Salem, OR	Free iPro clinic management; Nurse-in-the-Office.	M.C.	Medicare	7/23/2009	Pump, Insulin	not available
Radhakrishnan, Latha M.D	Physicians Building Group	Salem, OR	Free iPro clinic management; Nurse-in-the-Office.	O.W.	CHAMPVA	4/8/2008	Pump, Insulin	not available
Ravuri, Rajesh	North Bend Medical Center	Coos Bay, OR	Free iPro clinic management; Above-fair market value training payments; CTD; dinners and lunches.	J.R.	Medicare	2/25/2011	Pump, Insulin	Model: 523R SN: PAR471201U
Ravuri, Rajesh	North Bend Medical Center	Coos Bay, OR	Free iPro clinic management; Above-fair market value training payments; CTD; dinners and lunches.	D.H.	Medicare	10/18/2010	Pump, Insulin	not available
Theen, James W.	Independently owned clinic	Medford, OR	Above-fair market value training payments (Gina Jones); Nurse-in-the-Office; Free iPro clinic management.	A.S.	Medicare	3/25/2008	Pump, Insulin	not available
Theen, James W.	Independently owned clinic	Medford, OR	Above-fair market value training payments (Gina Jones); Nurse-in-the-Office; Free iPro clinic management.	R.H.	Medicare	4/28/2009	Pump, Insulin	not available

Key for References to Prohibited Relationships

"Above fair market value training payments" refers to the practice of paying fees to providers, practices and centers at above fair market value rates for services not actually needed or received, with a purpose of inducing referral sources to order Medtronic products (explained in further detail in the 2AC, § I.B.2). The contractor or employee who administered the training is identified in parenthesis.

"Free iPro clinic management" refers to the practice of providing free services to providers, practices, and centers, to set up and run (either all or in part) of an "iPro clinic" session, where patient visits are scheduled for the insertion of an iPro GCM, allowing the referral source to bill services to government healthcare programs at either no additional effort, or less additional effort, and enjoy additional revenue opportunities, with a purpose of inducing the referral source to order Medtronic products (explained in further detail in the 2AC, § I.B.1).

"Nurse in the office" refers to the practice of providing free nurse and case management services to referral sources, with purpose of inducing referral sources to order Medtronic products (explained in further detail in the 2AC, § I.B.3).

"CTD" refers to a practice of offering free incentives through the Connect the Dots program, including free equipment and free trips to symposiums in luxury locations, with a purpose of inducing referral sources to order Medtronic products (explained in further detail in the 2AC, § I.B.3).

"Free lunches/dinners, free supplies, paid trips or paid speaker" refers to the practice of providing other free incentives to referral sources, including by using a marketing budget provided by Medtronic and the insulin manufacturer, Eli Lilly, with a purpose of inducing referral sources to order Medtronic products (explained in further detail in the 2AC, § I.B.3).

Appendix B		
State	**State FCA statute**	**State Medicaid Anti-Kickback Prohibitions**
California	California False Claims Act, Cal. Gov. Code § 12651(a), *et seq.*	Cal. Bus. & Prof. Code § 650 *et seq* ; Cal. Welfare & Inst. Code § 14107.2; Medi-Cal Provider's Manual at 2; Medi-Cal Provider Agreement ¶¶ 2, 20
Colorado	Colorado Medicaid False Claims Act, Colo. Rev. Stat. § 25.5-4-305, *et seq.*	Colo. Stat. § 25.5-4-414; Colo. Med. Asst. Prog. Manual, Gen. Provider Info. and Requirements, at 14; Colo. Med. Assist. Prog. Provider Participation Agreement §§ A, I, K, & at 24
Connecticut	Connecticut False Claims Act for Medical Assistance Programs, Conn. Gen Stat. § 17b-301a, *et seq.*	Conn. Gen. Stat. § 53a-161d; Reg. Conn. State Agencies § 17-83k-1*et seq.* ; Conn. Gen. Stat. § 53a-161d; Reg. Conn. State Agencies § 17-83k-1et seq.; Conn. Med. Assist. Prog. Provider Manual, ch. 2, § 17b-262-533; Conn. Med. Assist. Prog. Provider Agreement ¶¶ 1-2, 26-31
D.C.	District of Columbia False Claims Act, D.C. Code § 2-381, *et seq.*	D.C. Code § 4-801(c); Code of D.C. Muni. Reg. §§ 29-1301.1, 2; Code of D.C. Muni. Reg. § 29-1399; D.C. Dept. of Health Care Fin.: Durable Med. Equip. Billing Manual §§ 4.3, 4.7; D.C. Dept. of Health Care Fin. Medicaid Provider Agreement at 20-21, 24
Delaware	Delaware False Claims and Reporting Act, 6 Del. Code § 1201(a), *et seq.*	31 Del. Code § 1005(b); Contract for Items or Servs. Delivered to Del. Med. Assist. Prog. Eligibles in the Dep't of Health and Soc. Servs. ¶ 3
Florida	Florida False Claims Act, Fla. Stat. § 68.082(2), *et seq.*	Fla. Stat. §§ 409.920(2)(a)(5), 409.907; Fla. Admin. Rule 59G-9.070(7)(p); Fla. Medicaid Provider Gen. Handbook at 2-12, 2-57; Fla. Medicaid Provider Enrollment App. at 9
Georgia	Georgia False Medicaid Claims Act, Ga. Code § 49-4-168, *et seq.*	Ga. Code § 49-4-146.1; Medicaid Manual, Part 1, Policies and Procedures for Medicaid/PeachCare for Kids, Definitions No. 1, 27, 47; §§ 106(B), (E), (MM); 404(X); 408(B); Dep't of Comm. Health., Div. of Med. Assist. Statement of Participation § 2(A)
Hawaii	Hawaii False Claims Act, Haw. Rev. Stat. § 661-21(a), *et seq.*	Haw. Rev. Stat. § 346-43.5; Code of Haw. §§ 17-1704, 7-1736; Haw. Medicaid Provider Manual § 2.8.2; Haw. State Medicaid Prog. Provider Agreement and Condition of Participation, pt. B, ¶ 1 & pt. C
Illinois	Illinois False Claims Act, 740 Ill. Comp. Stat. § 175/3(a), *et seq.*	305 Ill. Comp. Stat. § 5/8A-3(a),(b); 89 Ill. Admin. Code § 140.44(a); 89 Ill. Admin. Code. § 140.35; Handbook for Providers, ch. 100 (Gen. Policies and Procedures), § 136; Agreement for Participation: Ill. Med. Assist. Prog. ¶¶ 3, 6, 11, 16
Indiana	Indiana False Claims and Whistleblower Protection Act, Ind. Code § 5-11-5.5-2(b), *et seq.*	Ind. Code. §§ 12-17.6-6-12, 12-15-22-1 – 12-15-44-1, & 12-14.6-6-2; 405 Ind. Admin. Code § 1-1-4(a)(6)(E), (H); Ind. Health Care Prog. Durable Med. Equip. Provider Enrollment and Profile Maintenance Packet at 12, 14, 17
Louisiana	Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. § 46:437, *et seq.*	La. Rev. Stat. §§ 438.2, 46:437.11, -.14; 50 La. Admin. Code §§ 4145, 4147; La. Medicaid Prog. Manual §§ 1.1, 1.3; La. Provider Agreement, PE-50 Addendum § 10, 26, 27
Maryland	Maryland False Health Claims Act, Md. Code. Ann., Health-Gen. § 2-601, *et seq.*	Md. Crim. Law §§ 8-511, 8-512; Code of Md. Reg. § 10.09.36.08; Md. Med. Assist. Provider Handbook at 58, 63; Provider Agreement for Participation in Md. Med. Assist. Prog. at 1
Massachusetts	Massachusetts False Claims Act, Mass. Gen. Laws ch. 12, § 5B, *et seq.*	Mass. Gen. Laws ch. 118E § 41; 130 Mass. Code Reg. § 450.249(b); Commonwealth of Mass. MassHealth Provider Manual Series, ch. 2, §§ 450.249, 450.261; Mass. Med. Prog. Provider Agreement and Acknowledgement of Terms of Participation § 1
Michigan	Michigan Medicaid False Claims Act, Mich. Comp. Laws § 400.601, *et seq.*	Mich. Comp. Laws § 400.604; Mich. Dept. of Comm. Health, Medicaid Provider Manual at 10, 47; Med. Assist. Provider Enrollment & Trading Partner Agreement § 13

Minnesota	Minnesota Medicaid False Claims Act, Minn. Stat. § 15C.01, *et seq.*	Minn. Stat. § 62J.23; Minn. Rule § 52221.0700; Minn. Medicaid Provider Manual, Provider Basics, Provider Requirements section (online only); Minn. Health Care Programs Provider Agreement §§ 2, 24, 28
Montana	Montana False Claims Act, Mont. Code § 17-8-401, *et seq.*	Mont. Code § 45-6-13; Admin. Rules of Mont. §§ 37.85.401, 37.85.501; Gen. Info. for Providers: Medicaid and Other Med. Assist. Programs at 3.8; Mont. Health Care Programs [Medicaid, HMK *Plus* /Children's Medicaid, and HMK/CHIP] and MHSP Provider Enrollment Agreement and Signature Page at 19
Nevada	Nevada False Claims Act, Nev. Rev. Stat. § 357.040(1), *et seq.*	Nev. Rev. Stat. §§ 422.560, 422.410, 422.540, 422.580; Div. of Health Care Fin. and Policy, Medicaid Serv. Manual § 102; Nev. Medicaid and Nev. Check Up Provider Contract § 1.1
New Jersey	New Jersey False Claims Act, N.J. Stat. § 2A:32C-1, *et seq.*	N.J. Stat. § 30:4D-17; N.J. Admin. Code § 10:49-9-10, 10:49-11.1(d); Provider Agreement Between N.J. Dep't of Health and Senior Servs. ¶ 1
New Mexico	New Mexico Medicaid False Claims Act, N.M. Stat. Ann. § 27-14-1 *et seq.* & New Mexico Fraud Against Taxpayers Act, N.M. Stat. Ann. § 44-9-1, *et seq.*	N.M. Stat. §§ 30-44-7, 30-44-8, 27-11-3; N.M. Admin. Code §§ 7.1.5.9, 8.351.2 *et seq.* ; N.M. Med. Assist. Div. Prog. Policy Manual, ch. 302, §§ 8.302.1.11, 8.302.1.20(B)(12); N.M. Med. Assist. Div. Provider Agreement §§ 1.1, 8.1 – 8.4
New York	New York False Claims Act, N.Y. State Fin. Law § 187, *et seq.*	N.Y. Soc. Serv. Law §§ 366-d, 366-f; 18 N.Y. Codes, Rules, and Reg. §§ 518.1, 515.2; N.Y. State Medicaid Prog.: Info. for all Providers: Gen. Policy at 26-27, 63; N.Y. State Medicaid Physician Request for Enrollment at 5
North Carolina	North Carolina False Claims Act, N.C. Gen. Stat. § 1-605, *et seq.*	N.C. Gen. Stat. § 108A-63(g); 10A N.C. Admin Code §§ 22F.0201, 22F.0602, 22F.0604; N.C. Div. of Med. Assist.: Durable Med. Equip. and Supplies: Medicaid and Health Choice Clinical Coverage Policy No. 5A, § 7.1
Oklahoma	Oklahoma Medicaid False Claims Act, 63 Okla. St. § 5053, *et seq.*	56 Okla. Stat. § 1005(A)(6); Okla. Admin. Code §§ 317:30-3-2a, 317:30-3-18, 317:30-3-19; Okla. Health Care Auth. Provider Billing and Procedure Manual, ch. 17, at 17-320; SoonerCare Gen. Provider Agreement §§ 4.1(C), 5.2(D), 5.2(P), 5.3, 8.1
Rhode Island	Rhode Island False Claims Act, R.I. Gen. Laws § 9-1.1-1, *et seq.*	R.I. Gen. Laws §§ 40-8.2-3(a)(2), 40-8.2-5; Code of R.I. Rules § 15-040-08; R.I. Dept. of Hum. Serv. Code of Rules §§ 0300.40.15, 0300.40.20; State of R.I. Exec. Off. of Health and Hum. Serv. Provider Agreement Form §§ 1, 15
Tennessee	Tennessee Medicaid False Claims Act, Tenn. Code §71-5-182(a)(1), *et seq.*	Tenn. Code § 71-1-120; Tenn. Rules and Reg. §§ 1200-13-1-.05, 1200-13-1-.21; State of Tenn., Dep't of Fin. and Admin., Med. Assist. Participation Agreement (Medicaid/TennCare Title XIX Program) for Inpatient and Outpatient Hospital Serv. §§ I(D), I(E), III(A), III(F)
Texas	Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code § 36.002, *et seq.*	Tex. Occ. Code § 102.001 *et seq.* ; 1 Tex. Admin. Code §§ 371.27, 371.1707, 371.1709, 317.1711, 317.1713; Tex. Provider Procedures Manual, vol. 1, at 1-36, 1-37 – 1-42; Tex. Medicaid Provider Enrollment App. at 3-1 – 3-2, 3-5
Virginia	Virginia Fraud Against Taxpayers Act, Va. Code § 8.01-216.1, *et seq.*	Va. Code § 32.1-315; 12 Va. Admin. Code § 30-10-690; Va. Dept. of Med. Assist. Serv. Provider Manual for Durable Med. Equip. and Supp., ch. 1, at 20 & Appx. A at 1, 11; Commonwealth of Va. Dept. of Med. Assist. Serv. Med. Assist. Program: Durable Med. Equip. and Supp. Participation Agreement § 8
Wisconsin	The Wisconsin False Claims for Medical Assistance Law, Wis. Stat. § 20.931, *et seq.*	Wisc. Stat. § 49.49(2); Wisc. Admin. Code, Dep't of Health Serv. §§ 406.02(4), 106.06; Wisc. Medicaid Pers. Care Handbook at 3; Wisc. BadgerCare Plus and Medicaid Online Durable Med. Equip. Handbook, Topic Nos. 13277, 214; Wisc. Medicaid Provider Agreement and Acknowledgement of Terms of Participation §§ 2, 5